
STRENGTHENING THE SCIENTIFIC REVIEW PROCEDURES OF THE NIH INTRAMURAL RESEARCH PROGRAM

Consultant Panel to the Advisory Committee
to the Director, NIH

December 1989

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Duke University Medical Center

DURHAM NORTH CAROLINA
27710

DEPARTMENT OF BIOCHEMISTRY

December 19, 1989

Dr. William Raub
Acting Director
National Institutes of Health
Shannon Building
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Raub:

I am pleased to transmit to you the final report of the ad hoc consultant panel to the Advisory Committee to the Director, NIH, on "Strengthening the Scientific Review Procedures of the NIH Intramural Research Program".

The panel charge was to examine all aspects of the current NIH intramural scientific review procedures and to make recommendations for strengthening the review process. As part of its mandate, the panel also was to consider the recommendations of the National Academy of Sciences, Institute of Medicine (NAS/IOM) for modifying the intramural review process, to determine whether the NAS/IOM recommendations would strengthen the intramural research program, and if so, how they could be implemented most effectively.

The panel report reviews the genesis of this issue and the substantive information considered by the panel, including the NAS/IOM study, testimony on the intent of the study committee's recommendations, the regulations that define the current review procedures, and the application of those regulations to several of the NIH institutes. The report also examines proposals for improving the intramural review process that were presented by a working group from the NIH intramural research program. Many of these proposals were believed by the panel to be quite meritorious and these are reflected in the panel's final recommendations. Finally, the report provides the deliberations of the panel, and its summary recommendations for strengthening the scientific review procedures of the NIH intramural research program.

The panel's recommendations are intended to enhance existing review procedures and should not be interpreted as a minimum set of guidelines in and of themselves. The panel found the existing procedures to be on the whole sound and sought to provide its guidance on how these procedures could be improved.

Dr. William Raub
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In closing, I would like to emphasize a belief of the panel that is related to the broader issue of maintaining the scientific excellence of the NIH intramural research program. Although rigorous scientific review procedures lead to greater research accountability, the strength of the NIH intramural research program ultimately lies with the talent of the scientists who oversee and guide the enterprise. The panel fully concurs with the NAS/IOM finding that the responsibilities of the scientific director require both scientific vision and well-honed management skills and endorses the NAS/IOM recommendation that additional compensation should be available to recruit and retain scientists of the highest caliber.

The panel adopted the report unanimously and trusts that you will find the recommendations useful in strengthening the NIH intramural research program.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Robert L. Hill".

Robert L. Hill, Ph.D.
Chairperson
Consultant Panel of the
Advisory Committee to the
Director, NIH

RLH/bta

**Members of the Consultant Panel to the
Advisory Committee to the Director, NIH**

*Strengthening the Scientific Review Procedures of the
NIH Intramural Research Program*

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- B: September 5, 1989, Meeting Agenda
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- D: DHHS Manual Transmittal Sheet, Chapter 3005, *Review and Evaluation of Intramural Research By Boards of Scientific Counselors*. This document describes the current regulations governing the NIH intramural scientific review procedures.

- E: *Working Paper for the NIH Director's Advisory Panel Evaluating the Review Process of NIH Intramural Programs.* This document was prepared by NIH staff for the Consultant Panel's consideration and suggests changes to the current scientific review procedures.
- F: *Review and Evaluation of Intramural Research - 1989.* This document was prepared by the NIH Office of Intramural Research and provides a survey and analysis of intramural evaluation in 1989.
- G: Side-by-side comparison. This iteration compares the Chapter 3005 procedures with the NIH Working Paper proposals and the final recommendations of the Consultant Panel.

EXECUTIVE SUMMARY

Executive Summary

Background

Intramural research at the National Institutes of Health (NIH) has been reviewed by committees of scientists from outside NIH since 1956, when the first committees, called boards of scientific counselors, were appointed to review intramural research in the individual institutes. These boards of scientific counselors are public advisory committees established under provisions of the Federal Advisory Committee Act (Public Law 92-463). They review, discuss, and evaluate research projects and programs conducted by NIH as well as intramural research programs of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) located on the NIH campus. The reviews include evaluation of the work of individual scientists as well as of the quality of the research itself.

During the development of the fiscal year (FY) 1989 President's Budget, the Office of Management and Budget (OMB) requested the Department of Health and Human Services (DHHS) to evaluate strategies to strengthen the scientific excellence of the NIH intramural laboratories through an independent study by the National Academy of Sciences and the Institute of Medicine (NAS/IOM). In December 1988, NAS/IOM issued its report, *A Healthy NIH Intramural Program: Structural Change or Administrative Remedies?* Although the study concluded that "the intramural program has made and continues to make invaluable contributions to our knowledge and understanding of basic biological processes and their dysfunction in disease," the report also expressed concerns regarding the accountability and independence of the scientific review procedures of the NIH intramural research program. Among its several recommendations, the NAS/IOM study committee offered two that specifically addressed the NIH scientific review procedures:

"A panel chaired by a member of the NIH Director's Advisory Committee should be established to monitor the intramural research program review"; and

"Each of the scientific directors and their intramural programs should be reviewed as a whole every four years by an external group. The review report should be submitted to the director of the relevant institute,

the NIH Deputy Director for Intramural Research, the Director of NIH, and the Director's Advisory Committee."

In response to these two recommendations, the Director of NIH established a Consultant Panel to the Advisory Committee to the Director (DAC), NIH, to examine all aspects of the current NIH intramural scientific review procedures and to make recommendations for strengthening the intramural review process.

A meeting of the Panel was held at NIH on September 5, 1989. In advance of the meeting, the Panel was provided with briefing materials including the NAS/IOM report; Chapter 3005 of the DHHS manual, which establishes the policy and procedures for outside review and evaluation of intramural research at NIH; a working paper prepared by NIH staff that suggested changes to the current review procedures; and a survey and analysis of intramural evaluation prepared by the NIH Office of Intramural Research.

During this meeting, the Panel heard testimony regarding the intent of the NAS/IOM study committee's recommendations from Dr. Robert Petersdorf, a member of the original NAS/IOM study committee. The Panel also heard presentations from senior scientists from the NIH institutes, including institute directors, and the scientific directors of the intramural research programs.

Summary of Issues Discussed

In the course of its deliberations, the Panel addressed the two study committee recommendations and several related issues raised in the NAS/IOM report. It examined the procedures for selecting reviewers and the mechanisms for ensuring that there is an appropriate response to each review. The Panel was concerned about negative perceptions of the review procedures, particularly those that called into question the accountability and independence of the intramural review process. Among the issues addressed by the Panel were the following:

- How should counselors be selected and what is the optimum composition, size, and length of service of the boards of scientific counselors?
- Is there a need for a minimum set of codified standards that would apply across all the institutes?
- What kind of orientation do counselors receive?
- How should the review be structured, to whom should the report of the review be delivered, and what should be the mechanisms for following through?
- What is the most appropriate mechanism for responding to the report of the review by the boards of scientific counselors?

The Panel considered the perception expressed by some individuals outside NIH that the NIH intramural scientific review process is less demanding than the extramural research peer review process. Questions regarding the rigor,

uniformity, and followthrough of the review procedures were also discussed by the Panel.

The Panel also found that the tradition of scientific review at the NIH dates back to the establishment of the first boards of scientific counselors in 1956, and that the review procedures have been strengthened periodically through the publication of revised policy and procedures contained in Chapter 3005.

Finally, the consultants felt strongly that the extramural and intramural research communities were sufficiently unique to require different approaches to scientific evaluation. Unlike the extramural community's emphasis on prospective peer review and its focus on *potential*, the NIH intramural scientific review process is a critique of past *performance* designed to elicit counsel regarding current and future activities.

The following Panel recommendations for strengthening the intramural review procedures represent new proposals or modifications to existing requirements outlined in Chapter 3005.

Summary of Recommendations

Monitoring of the Intramural Research Program

1. An ad hoc Consultant Panel to the Advisory Committee to the Director, NIH, should be convened in 2 years, and periodically thereafter, to review progress on the following recommendations and changes in the intramural scientific review process.

Evaluation of the Scientific Director

2. The scientific and administrative performance of the scientific directors should be evaluated every 4 years by the boards of scientific counselors. The chairperson of the board of scientific counselors should provide the institute director with a written evaluation of the scientific director, including a discussion of the overall direction of the intramural program and the efficacy of the review process. The institute director may request an evaluation of the scientific director by the chairperson each year.

Boards of Scientific Counselors

3. Nominations for the board of scientific counselors should be provided to the director of the institute by the chairman of the board of scientific counselors, with the advice of the scientific director. The institute director and the Deputy Director for Intramural Research, NIH, should provide a final review and approval of the list of nominees. The appointment authority, with the exception of the National Cancer Institute (NCI), should remain with the Director, NIH. Ad hoc reviewers should be selected by the chairperson of the board of scientific counselors, with the advice of the scientific director.

4. The term of office for scientific counselors should be increased to 5 years to facilitate continuity of review and to allow the review of specific programs more than once by the same counselor(s).
5. The institutes should, to the extent possible, increase the number of individuals serving on their boards of scientific counselors.
6. Upon completion of their appointment, scientific counselors should be surveyed by the chairperson of the board of scientific counselors on issues of program quality and the scientific review process. This survey information should be provided to current board members.

Review Function and Process

7. Uniform standards for scientific review procedures should be developed and codified.
8. Within certain specific requirements, each institute should be allowed to develop its own procedures for the organization and structure of the scientific review meetings. The Deputy Director for Intramural Research, NIH, should evaluate the institutes' procedures to ensure that the uniform requirements of the NIH are met and to communicate the experiences of the different processes to all of the scientific directors.
9. Scientific counselors should be provided with orientation guidelines that describe the review procedures, the goals of the process, and the responsibilities of counselors. These guidelines should be published by the Deputy Director of Intramural Research, NIH.
10. The boards of scientific counselors should provide evaluation and advice on science, specific projects (including new areas of development), tenure and promotion decisions, resource allocation, and other administrative matters.
11. All board members should be provided with a summary of the organization of the laboratory to be reviewed; the various sections; all personnel, space usage, operating budget, and outside contracts; and Cooperative Research and Development Agreements. Each scientist being reviewed should supply details of ongoing work, a curriculum vitae, reprints of the three to five most important recent publications, and an analysis of the amount of support staff and space that scientist uses.
12. Before the board adjourns, an oral summary of the review should be presented to the scientific director; the institute director; and the Deputy Director for Intramural Research, NIH; or their designees.
13. Within a month of adjournment, the board should provide a written report of its review to the scientific director. Those portions of the report that pertain to particular laboratory/branch chiefs should be provided to them by the scientific director. The scientific director and the laboratory/branch chief should discuss the evaluations and recommendations in the report. The

scientific director may also choose to discuss appropriate parts of the report with section chiefs and individual scientists who have been reviewed.

14. Within 6 months of receiving the board's report, but prior to the next board of scientific counselors' meeting, the scientific director should respond to the board indicating areas of agreement and disagreement and any possible changes that may be undertaken. A copy of the report and the response of the scientific director should be sent to the director of the institute; the Deputy Director for Intramural Research, NIH; the Director, NIH; and the institute's national advisory council.
15. No later than 1 year after the review, a written response should be provided to the board of scientific counselors by the scientific director, summarizing the results of any actions taken.
16. The institute's national advisory council should be provided an overview of the institute's intramural research program at least once a year. The overview should include, at a minimum, a discussion of the board of scientific counselors' report and the response of the scientific director.

REPORT OF THE CONSULTANT PANEL

Report of the Consultant Panel

Background

During the development of the FY 1989 President's Budget, the OMB requested DHHS to evaluate strategies to strengthen the scientific excellence of the NIH intramural laboratories, through an independent study by NAS/IOM. In December 1988, NAS/IOM issued its report, *A Healthy NIH Intramural Program: Structural Change or Administrative Remedies?* (Excerpts from the report are included in appendix A.)

The NAS/IOM committee found that "the NIH intramural research program is a distinctive and valuable component" of the Nation's biomedical research enterprise, and that it "continues to make invaluable contributions to our knowledge and understanding of basic biological processes and their dysfunction in disease." The committee recommended administrative changes in the existing intramural research program structure that address problems associated with increased flexibility in personnel administration, maintaining administrative efficiency, and improving the review of the intramural research program.

Among several recommendations that were intended to maintain the high scientific standards of NIH, the NAS/IOM committee suggested two that it felt "essential to credible quality assurance" for the intramural scientific review process:

✓ "A panel chaired by a member of the NIH Director's Advisory Committee should be established to monitor the intramural research program review"; and,

✓ "Each of the scientific directors and their intramural programs should be reviewed as a whole every four years by an external group. The review report should be submitted to the director of the relevant institute, the NIH Deputy Director for Intramural Research, the Director of NIH, and the Director's Advisory Committee."

Introduction

In response to these two recommendations, the Director of NIH established a Consultant Panel to the DAC to determine whether the NAS/IOM

recommendations might strengthen the NIH intramural research program and, if they might, how they could be implemented most effectively. The Director also requested the Consultant Panel to "examine all aspects of the current NIH intramural scientific review procedures and to make recommendations for strengthening the intramural review process."

A meeting of the Panel was held at NIH on September 5, 1989. (See appendixes B and C for the agenda and a list of presenters.) The Panel addressed the two NAS/IOM recommendations, as well as additional issues concerning the intramural scientific review procedures. It examined the procedures for the selection of reviewers to serve on boards of scientific counselors, the mechanisms that are in place to communicate the results of the scientific reviews made by the boards, and the implementation of their recommendations. The Panel also was concerned about negative perceptions of the review procedures, particularly those that called into question the accountability and independence of the intramural review process. Thus the Panel set out to examine fully the scientific review procedures of the NIH intramural program and to develop a report with recommendations for strengthening the review process.

Information Considered by the Consultant Panel

In advance of the meeting, the Panel was provided with briefing materials including the NAS/IOM report; Chapter 3005 of the DHHS manual, which establishes the policy and procedures for outside review and evaluation of intramural research at NIH; a working paper prepared by NIH staff that suggested changes to the current procedures; a documented survey and analysis of intramural evaluation prepared by the NIH Office of Intramural Research; and a side-by-side comparison of procedures in Chapter 3005 and the proposals in the working paper. (See appendixes D, E, F, and G.)

During its meeting the Panel heard testimony on the intent of the NAS/IOM study committee's recommendations from Dr. Robert Petersdorf, a member of the original study committee. The Panel also heard presentations from Dr. Michael Millman (director of the NAS/IOM study) and several senior NIH scientists, including institute directors and the scientific directors of the intramural research programs. The following sections summarize the information considered by the Panel.

The NAS/IOM Report

The NAS/IOM study committee reported the following principal findings on the NIH intramural research program:

- "The intramural program has made and continues to make invaluable contributions to our knowledge and understanding of basic biological processes and their dysfunction in disease."
- "A high quality intramural program is a distinctive and valuable component of the nation's overall biomedical research effort."
- "The quality of the program, however, varies by scientific sub-field. To improve the overall quality and maintain the excellence and credibility of the program, attention must be paid to a continuing process of quality review and how it can be used to improve the allocation of resources."
- "The scientific directors of the institutes, who most directly manage the intramural program, are essential keys to their success. Therefore, finding ways to ensure the selection and retention of distinguished scientific leaders for these posts is essential."

The study committee also found that despite the stature of the scientific counselors and ad hoc consultants that serve in the NIH review process, the "fact that they are nominated by the scientific director of the institute whose program will be under review compromises the external credibility of their report." Also, despite recent improvements made by NIH through feedback mechanisms to the board of scientific counselors on the implementation of their recommendations,

the study committee felt that “the scientific director is at no time accountable to anyone outside the institute.”

These concerns led to the two principal NAS/IOM recommendations to strengthen the NIH intramural review process: first, the creation of a monitoring panel chaired by a member of the DAC; and second, that the scientific directors and their intramural programs should be reviewed as a whole every 4 years by an external group.

According to the NAS/IOM report, the proposed monitoring panel’s function would be to oversee the integrity of the review process, not to replicate the activities of the boards of scientific counselors. The oversight function “should focus on areas that are most vulnerable to criticism, namely the selection of the reviewers and the appropriate response to recommendations.”

The NAS/IOM study committee also believed that the proposed quadrennial review of the scientific directors and their intramural programs was necessary “because of the importance of ensuring the vitality of the intramural program . . . through a process that would ensure vigorous leadership.”

The role of the scientific directors was seen as vital to the success of the intramural programs, as reflected in the following recommendation in the NAS/IOM report:

“. . . the responsibility of the scientific director requires having the scientific vision needed to allocate intramural resources productively, as well as function as a highly skilled manager. To recruit and retain scientists with this extraordinary set of attributes, the committee recommends that those holding the position of scientific director receive additional compensation.”

Testimony of Dr. Petersdorf

In his presentation to the Panel, Dr. Petersdorf (an NAS/IOM study committee member) indicated that a key issue for the NAS/IOM study committee had been how the review process of the intramural research program is perceived by individuals outside NIH. Those perceptions include the possibility of less rigorous review of intramural than extramural research, unevenness of intramural reviews among NIH institutes, inadequate usage of reviews, and the potential conflict of interest in selecting scientific counselors. Dr. Petersdorf indicated that the NAS/IOM study committee also had been left with the impression that the boards of scientific counselors do not have a *modus operandi* that can be described easily, and that there is considerable variability in how the review process is pursued.

The NAS/IOM committee sought the institutionalization of a mechanism for external peer review of intramural research that would function at arm’s length from the officials whose programs were under review to eliminate the possibility of conflict of interest (real or apparent) in the behavior of members of the external

review bodies. The goal embodied in the NAS/IOM committee recommendations was that the direct responsibility for, and control of, the process of external evaluation of intramural research be transferred from the scientific directors to the Director of NIH.

The NAS/IOM study committee also believed that any changes in the current intramural program review procedures must be made carefully. The organization, structure, and location of the intramural research program, for example, are unique and require a system of peer review that is adapted to the program's special characteristics and that differs from the process in place for project-based extramural research.

DHHS Manual Chapter 3005

Intramural research at NIH has been reviewed by committees of scientists from outside NIH since 1956. In that year the first committees, called boards of scientific counselors, were appointed to review intramural research in the individual institutes. Board procedures have evolved over the years. On March 4, 1985, the original version of DHHS Manual Chapter 3005 (*"Review and Evaluation of Intramural Research by Boards of Scientific Counselors"*) was issued to establish policy and procedures for the evaluation of intramural research by the boards. Subsequently, Public Law 99-158, the Health Research Extension Act of 1985, was enacted (on November 20, 1985). It included a provision making mandatory what was then standard policy on review of intramural research.

The boards of scientific counselors are public advisory committees established under provisions of the Federal Advisory Committee Act (Public Law 92-463). The boards review, discuss, and evaluate research projects and programs conducted by NIH and by ADAMHA intramural programs located on the NIH campus. The reviews include evaluation of the work of individual scientists as well as the quality of the research itself.

It is the policy of NIH that the intramural programs of the agency be reviewed regularly by highly qualified outside scientists. The reviews include the quality of the research and the accomplishments of individual scientists. This policy is reinforced by section 492(b) of the Public Health Service (PHS) Act:

The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that —

1. the reviewing entity be provided a written description of the research to be reviewed, and
2. the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity.

These reviews, and any resulting recommendations, should be included in a written report submitted to the scientific director, who will transmit it to the institute director; the NIH Deputy Director for Intramural Research; and the Director, NIH. In addition, as required by the PHS Act, the institute will provide written descriptions of the research reviewed by the board of scientific counselors, and results of that review to its national advisory council. Such communications should be made to the council at least annually. Also, as stated in the PHS Act, the advisory council "may on the basis of the materials provided under Section 492(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research."

The Chapter 3005 procedures require that the "primary consideration (for) scientific qualification for board membership shall be international recognition as an authority in the fields under review." The section also requires each board to exhibit reasonable balance in membership with respect to gender, race, and geographical distribution of its member institutions. Board members are nominated by the institute scientific director and, with the exception of NCI, approved by the institute director and the Deputy Director for Intramural Research, NIH, and appointed by the Director, NIH. Under the PHS Act, the Director, NCI, has authority, in consultation with the National Cancer Advisory Board, to appoint members of NCI Boards of Scientific Counselors.

Chapter 3005 procedures also require boards to "meet often enough (ordinarily two or three times each year) to assure that the work of each intramural scientist on a permanent appointment in each laboratory or branch is reviewed at least once every four years." Each scientific director must submit to the Deputy Director for Intramural Research, NIH, a schedule of the proposed dates of review of each laboratory or branch in the institute or division covering the next 4-year review cycle. This schedule must be updated annually and submitted by September 1 each year.

The following information must be provided to each board reviewer in advance of the meeting:

- For each laboratory or branch being reviewed—a staff list of all employees, including name, occupational specialty, type of appointment and grade; and a list of all contracts that support the work of the laboratory or branch.
- For each scientist whose work is to be reviewed—a current curriculum vitae, bibliography, and recent relevant reprints; a succinct summary of current research and statement of future plans; and the amount of technical and postdoctoral support required by each scientist.

A copy of the last review of the laboratory or branch should be available to the board. The conference report for this section of the PHS Act notes that "the written description should present the overall past accomplishments of the laboratory and its investigators since the last review was conducted. The written description might also present the general aims, the objectives, and the projected

directions of the research projects to be conducted; appropriate background information on possible future research projects; a brief summary of the general research plan; and an indication of the importance of the research projects.

Every independent intramural scientist on a permanent appointment must be reviewed and evaluated. In general, the advice of the board of scientific counselors also should be obtained concerning scientists who are being considered for conversion to tenure, and the scientific director may ask the board to review the work of other staff scientists. Over time, the active program of each laboratory or other intramural research unit is to be reviewed.

The organization and structure of meetings of the board of scientific counselors is left to the discretion of the scientific director, but the reviewers should be given an opportunity to visit the facilities where the research is carried out.

Chapter 3005 sets forth the provisions to be followed in reporting the results of the reviews. The report of the board is to be a narrative critique from the chairperson of the board, following the outline preferred by the scientific director. Evaluations of individual investigators must address, at a minimum, the following questions: are good research questions being asked, are appropriate approaches being used to obtain answers, and are the resources available to this scientist appropriate to the accomplishments to date? These evaluations should be written by members of the board of scientific counselors or consultants and should reflect the collective views of the total board (or at least a majority).

Within 4 months of the review, the report is to be sent to the scientific director, who is responsible for transmitting it to the institute director; the NIH Deputy Director for Intramural Research; and the Director, NIH. The Office of Intramural Affairs distributes copies to the NIH Board of Scientific Directors and schedules its discussion by all members of that group.

At least annually, each institute transmits descriptions of the research that has been reviewed by its board(s) of scientific counselors during the preceding year to its national advisory council together with the results of the reviews. The results of the reviews and board recommendations may be reported to the council orally or in writing by the scientific director or the chairperson of the board. In written reports, the evaluation of individual scientists may, for privacy reasons, be omitted.

It is the responsibility of the scientific director to report to the board of scientific counselors the action taken in response to recommendations made by the board. This report shall describe actions taken or explain why it was found impossible or inadvisable to follow the recommendations.

Overview of NIH Intramural Scientific Review Procedures

Dr. Joseph E. Rall, Deputy Director for Intramural Research, NIH, provided the Panel with comments about the NIH intramural scientific review procedures, including the following key points:

- The relationship of a board of scientific counselors to the intramural research program it reviews is much different today than it was in the 1970's.
- Institutes differ somewhat in how they use their board of scientific counselors, in part because of organizational differences. Such an arrangement is valuable because it enables each institute to learn from others.
- Only distinguished and highly recognized scientists are considered for board appointments, and those appointments must be approved by the Deputy Director for Intramural Research, NIH, (or in the case of NCI, by the Director, NCI). Occasionally the Deputy Director for Intramural Research, NIH, suggests changes in the appointment of members.
- Scientific counselors provide scientific advice as well as recommendations on promotion and tenure, the best use of available resources, whether a particular laboratory should receive support, and certain administrative issues such as the length of a staff fellowship.
- Boards of scientific counselors are restricted from certain activities. For example, the boards can neither increase salaries of outstanding scientists nor directly hire outstanding scientists to develop new areas of the intramural program.
- Each scientific director pays careful attention to suggestions from the board, which helps strengthen his or her position in directing the scientific programs of the institute.
- Although the salary of a scientist in the intramural program cannot be summarily withdrawn, laboratory funding and support can. Scientists in the intramural program, like their counterparts in the extramural program, must compete for resources and are constantly required to do so.

The intramural program is, in certain ways, unique. For a scientist, becoming a tenured member of the program is a process that takes many years, during which time programs and resources are developed. During this time, candidates have the chance to demonstrate outstanding research competence. In this environment, both tenure candidates and tenured scientists have the opportunity to address difficult, long-term research goals that may not produce immediate results. Progress toward these goals, as well as the scientific achievements of each individual scientist, are continually reviewed. The institute, however, seeks to preserve the long-term goals of each designated program that may involve many scientists, as long as those goals remain appropriate. The research results that have emanated from this approach are evident. Dr. Rall suggested that any

attempt to improve the review process should be accepted only if it would clearly improve the quality of intramural research.

Unique Institute Characteristics

National Institute of Allergy and Infectious Diseases (NIAID)

Dr. John Gallin, Director of the Intramural Research Program in NIAID, provided the following comments on how intramural research is reviewed in that institute:

- The board, which meets twice a year, consists of eight scientific counselors and eight ad hoc reviewers. The members of the board are nominated by the Scientific Director, after staff consultation with the Director, NIAID, to the Deputy Director for Intramural Research, NIH, who approves the appointments.
- A chairperson, chosen by the scientific director from among those scientific counselors serving for a third or fourth year, selects the ad hoc reviewers for the upcoming meeting from a list drawn up by the scientific director, after staff consultations. The chairperson of the board of scientific counselors may add to or delete from the list of names.
- Participants receive, in advance, a briefing book from the scientific director describing the review process and a book for each laboratory under review. The latter book reviews past laboratory accomplishments; future directions; and administrative details on the space, support personnel, contracts, and—starting in December 1989—direct operating costs. Board members are provided with primary review assignments before arriving at NIH.
- At each year's initial session of the board of scientific counselors, the scientific director goes over the entire review process. Each laboratory is reviewed every 4 years. Following the opening session each laboratory chief makes an oral presentation, followed by presentations from selected senior scientists and individual candidates for tenure.
- Each board member meets privately with individual scientists, and each scientist has at least two interviews. However, every candidate for tenure, laboratory chief, and section head has three interviews. These interviews last 30 minutes to an hour and are held in the laboratory, where notebooks and other materials are available at the interviewer's request. Each board member then writes a 250- to 500-word evaluation of each scientist interviewed.
- The board also approves concepts for new contracts and for contracts up for renewal. The scientific director does not attend the board's closed executive session, so that the board may discuss the scientists interviewed and draw up final recommendations. In addition, selected board members write overviews of each section and laboratory reviewed at that session.

- In closed executive session the board discusses the laboratory summary overviews and provides each laboratory chief with a private evaluation, allows the individual to comment, and revises its evaluation if necessary.
- At the end of its meeting, the board also meets and discusses the reviews and its recommendations with the NIAID Director; the scientific director; and the Deputy Director for Intramural Research, NIH, or his designee.
- Before adjourning, the board submits all written reports to the scientific director and later sends back comments and evaluations on the review process itself.
- Within a month after the meeting ends, the final report is assembled. The scientific director then provides each scientist interviewed with the anonymous reports of the board members, discusses the review process, and gives an impression and evaluation of the scientist. The scientific director provides each section chief and laboratory chief with an evaluation of their scientific staff and the overview evaluation of their section/laboratory.
- Within 6 months of the last board meeting, the scientific director provides the board with an oral report, and within a year a written report, that documents the institute's followup activities in response to the board's recommendations. A copy of this summary board report is transmitted to the Director of NIAID, the NIH Deputy Director for Intramural Research, and the NIH Board of Scientific Directors within 6 months of the review. Once a year the NIAID National Advisory Council is briefed on the board's activities and the state of the institute's intramural program.

Previous discussions among the NIAID Director, Scientific Director, and Chairman of the NIAID Board of Scientific Counselors led to the conclusion that although a formal review of the scientific director was unlikely to work, the scientific director could provide either an oral or a written presentation to the board about the institute's work and how resources are allocated. An added recommendation was that once every 4 years the chairperson of the board of scientific counselors should prepare a consensus report, based on the board's views, of the state of the institute's intramural program and the review process undertaken by the board.

National Institute of Child Health and Human Development (NICHD)

Dr. Arthur Levine, Scientific Director, emphasized the following key points for review of intramural research at NICHD:

- The diversity of scientific research in NICHD requires a nine-member board of scientific counselors.
- Before each board meeting, board members receive a briefing book with information on overall resource allocation and current scientific accomplishments. The book contains reports of all site visits held since the previous board meeting.

- At twice-yearly board meetings, the scientific counselors review the institute's entire intramural program rather than specific laboratories.
- The board also reviews actual site visit reports prepared since the last meeting, followup reports to previous visits, and oral presentations by tenure candidates. In addition, generic issues such as policies for the review of intramural research, scientific misconduct, and animal care are discussed.
- Three laboratory site visits are conducted each year, each chaired by a different board member, resulting in a review of each of the institute's laboratories and branches once every 4 years. Often two or three other board members will participate in a site visit, together with up to 10 or 12 ad hoc visitors. The chairperson for the visit selects ad hoc reviewers from a list prepared by the scientific director and may add and delete names.
- Site reviewers receive a briefing book prepared by the laboratory and an orientation by the scientific director before the site visit takes place. This book contains detailed descriptions of the results of each tenured scientist's research, current work (goals, methods, etc.), and proposed future research. A detailed accounting of resources is also provided, as well as curriculum vitae, preprints, protocols, etc.
- The site visit, which lasts 2 days for each laboratory or branch, consists of 1-hour presentations by each tenured or tenure-candidate scientist. Reviewers also visit the laboratories, where they meet and talk with the staff and where they can view special techniques, equipment, and laboratory notebooks. Site reviewers meet with the laboratory chief and the scientific director to exchange views and impressions, and they draft the report before adjourning.
- The final report is sent to the scientific director, who transmits it to, and discusses it with, the laboratory chief; the laboratory chief in turn transmits relevant sections of the report to each investigator in the laboratory. A copy of the report is forwarded to the Director of NICHD; the Deputy Director for Intramural Research, NIH; and the other NIH scientific directors.
- At the next semiannual meeting of the board of scientific counselors, the report is distributed for discussion together with the written response of the laboratory chief.
- The scientific director provides the board with followup information 6 months later, i.e., 1 year after the visit. In addition, once a year the chairperson of the board of scientific counselors makes a report to the NICHD National Advisory Council on the review process and the main conclusions of that year's reviews.

National Cancer Institute (NCI)

Dr. Alan Rabson, Director of the Division of Cancer Biology and Diagnosis, presented the following highlights of intramural research review at NCI:

- Differences in the scientific review of intramural research programs at NCI can be attributed to the different organizational structure of the Institute. There is no separate division of intramural research at NCI; instead, the intramural research programs are located within three of the operating divisions—the Division of Cancer Biology and Diagnosis, the Division of Cancer Etiology, and the Division of Cancer Treatment. Each of these divisions also has an active extramural research program. The director of each division serves as the scientific director of both the extramural and the intramural research programs. Each division has its own board of scientific counselors that advises the division director on both intramural and extramural research programs. In the extramural program, the board is responsible for concept approval of all program initiatives such as Requests for Applications and Program Announcements for grants and Requests for Proposals for contracts.
- The NCI divisional boards of scientific counselors are larger than those of other institutes, ranging from 15 to 20 members. The members are appointed by the Director, NCI. Because their responsibilities also include the extramural program, it would be inappropriate for the board members to be approved by the Deputy Director for Intramural Research, NIH; however, he is provided with an informational copy of the list of proposed board members.
- Because the NCI boards are larger than those of the other institutes and must have members with a broad range of expertise to review extramural as well as intramural programs, it is not always appropriate for all of the members to attend each site visit. The board chairperson, with the advice of the Division Director, appoints a board member with appropriate expertise to be chairperson of the site visit team. Other board members with appropriate scientific expertise also participate in the site visit. Additional ad hoc members with special expertise in the research programs of the laboratory being reviewed are selected by the site visit chairperson, with advice from the Division Director and the chairperson of the full board. The site visit chairperson prepares the report and sends it to the Division Director. The report is then presented and discussed by the full board in closed executive session at the first scheduled meeting following the site visit. One year after the site visit, the Division Director reports back to the board on the actions taken in response to the site visit report.

Working Paper on Proposed NIH Intramural Scientific Review Procedures

Dr. Edward Korn, Director of the Division of Intramural Research of the National Heart, Lung, and Blood Institute (NHLBI), presented highlights of a working

paper prepared by representatives of the NIH intramural research program. This working paper provided the panel with a synopsis of current procedures and suggestions for improving the review process. It includes the following key points not already stated explicitly in Chapter 3005:

Composition of Boards

- The board of counselors should consist of six to eight members, each serving a 4-year term.
- The chairperson of the board of scientific counselors will be selected by the scientific director, with the advice of the institute director, usually from one of the members serving for a fourth year.
- Nomination of board members will be conducted with the advice of the chairperson of the board of scientific counselors.
- The board will be supplemented for each review with ad hoc reviewers selected by the chairperson of the board with the advice of the scientific director.

Frequency of Review Meetings

- Scientific reviews by the board of scientific counselors supplemented by ad hoc reviewers must be held at least semiannually.

Information Supplied to Boards of Scientific Counselors Before Meeting

- For each scientist to be reviewed, the briefing materials must also include a written summary of the presentation (emphasizing accomplishments since the last review) and space assignments.
- For each laboratory/branch being reviewed, the material must also include a summary of administrative organization, including space allocations, budget information, and Cooperative Research and Development Agreements.

Responsibilities of the Board of Scientific Counselors

- The board of scientific counselors is responsible for recommending both programmatic changes and changes in level of support for individual scientists, including conversions to tenure status and promotion.
- All conversions to tenure and promotions of the scientific staff within any one institute must be approved by the institute director and the NIH Board of Scientific Directors.
- The board of scientific counselors must also review and assess the performance of the scientific director, primarily based on reviews of the laboratories

and branches. In addition, at periodic intervals, the board will specifically review the scientific director and make a formal report to the institute director.

Review Format

- For the review process, the laboratory/branch chief will present an overview of the research activities. The review of individual scientists may be oral presentations to the assembled board followed by discussion, or a mixture of oral presentations and separate interviews with one or more members of the board and ad hoc reviewers.
- The board will hold executive sessions to discuss the merits of the individual presentations as well as broader aspects of the intramural program.
- The board may wish to meet with the laboratory/branch chiefs to clarify its understanding of the scientific presentations and to provide the laboratory/branch chiefs with an opportunity to respond to its questions before the final report is prepared.

Reporting of Results of Reviews

- Before the board adjourns, an oral summary will be presented to the scientific director. The institute director and the Deputy Director for Intramural Research, NIH, or their designees will be invited to these sessions. The board will provide a written report to the scientific director within 1 month of the review.

Followup

- The portion of the board's report that pertains to particular laboratory/branch chiefs will be provided to them by the scientific director. The scientific director and laboratory/branch chief will discuss the evaluations and recommendations in the report. The scientific director may also wish to discuss the report privately with one or more investigators under review.
- Within 6 months of receiving the report, the scientific director will respond to the board, indicating areas of agreement and disagreement and any possible changes that may be undertaken.
- The scientific director will transmit copies of the report and the scientific director's response to the institute director; the NIH Deputy Director for Intramural Research; and the Director, NIH, within 6 months of the review. The report will be distributed to the scientific directors of all the institutes and be discussed at a regularly scheduled meeting of the NIH Board of Scientific Directors.
- After 1 year, the scientific director will respond to the board in writing, summarizing the results of any actions taken.

- The written material reviewed by the board the previous year and the board's reports will be presented annually to the institute's national advisory council by the scientific director.

Review of the Scientific Director

- Once every 4 years, the chairperson of the board of scientific counselors will provide a written report to the institute director, evaluating the review process and the overall direction and major accomplishments of the intramural program. The institute director may request an evaluation of the scientific director by the chairperson each year.

Deliberations and Findings of the Consultant Panel

The Panel addressed the two specific recommendations of the NAS/IOM study committee, seeking to determine if the recommendations were appropriate for strengthening the intramural review procedures and, if so, how best to implement them. In addition, the Panel examined all aspects of the current scientific review procedures and considered ways for strengthening the process. After an extensive discussion of these points, the Panel outlined its full recommendations for changing the scientific review procedures of the NIH intramural research program.

Monitoring the Intramural Research Program Review

The Consultant Panel held a far-reaching discussion on the NAS/IOM recommendation that would establish a panel, chaired by a DAC member, to monitor the intramural research program review. The Consultant Panel recognized that the function of the proposed group would be to ensure the integrity of the process, not to replicate the activities of the boards of scientific counselors. The Panel was also aware that a principal concern of the NAS/IOM study committee was the selection of reviewers and the implementation of the boards' recommendations.

The discussion of this issue began with a review of the structure and function of the DAC, which was described as consisting of the committee chair and 16 appointed members. Eleven members are authorities knowledgeable in the fields of research pertinent to the NIH mission, and five are representatives of the general public. The DAC provides advice on policy matters pertinent to the NIH mission and makes recommendations concerning program development, NIH administrative regulation and policy, and other specific or general aspects of NIH policy.

The ensuing discussion elaborated on factors in favor of accepting the recommendation. The point was made that a standing panel of the DAC could meet periodically to assess the quality issues in the institutes by reviewing the appointments and reports of various boards in an orderly way. Individual members of the monitoring panel could be assigned institutes or divisions to monitor and serve as a channel to the DAC to keep it abreast of accomplishments and problems. The panel, as envisioned, would report problems discovered in the review process to the Director, NIH, and thereby bring about a uniformity in review—a condition that was of concern to the NAS/IOM study committee.

In counterpoint, questions were raised about the operational nature of the proposed monitoring panel. Would it receive summary details of the reports of the several boards of scientific counselors or the reports of the boards in their entirety? The subject of scope was also considered: 14 boards each meeting twice a year would produce 28 major reports, each a synopsis of a number of site

visits during which the actual quality assessment occurs. Would the DAC in its current form have sufficient resources to follow the intramural programs of all the institutes? How could the proposed panel truly monitor the review process without adding another layer to the process?

Serious concerns also were raised about how the responsibilities of the proposed DAC panel would compare with the legislatively mandated responsibilities of the institutes' national advisory councils. The Panel felt that quality issues related to the intramural programs were well within the purview of the national advisory councils' legal responsibilities. Reports of reviews completed by the boards of scientific counselors should be presented to the councils, which have the subsequent authority and responsibility to advise the institute directors.

Finally, the Consultant Panel discussed what role, if any, would be appropriate for the DAC to play in ensuring that the intramural review procedures continue to meet the standards of excellence envisioned by the NAS/IOM study committee. The Panel concluded that while the DAC should not have a continuing role of monitoring the review process as recommended in the NAS/IOM report, it should reexamine this issue in 2 years and periodically thereafter to examine the progress made in strengthening the intramural scientific review procedures.

Evaluation of the Scientific Director

The Consultant Panel next addressed the NAS/IOM study recommendation that called for a quadrennial review of the scientific directors and their intramural programs by an external group.

The NAS/IOM study committee found that such a review is necessary to ensure the vitality of the intramural program. Under the leadership of the institute director, and with the advice of the board of scientific counselors, the scientific director exercises a decisive role in influencing the intramural program. The NAS/IOM report noted, "The responsibility of the scientific director requires that he/she have the scientific vision needed to allocate intramural resources productively, as well as to function as a highly skilled manager." The NAS/IOM study committee also recommended that scientific directors receive additional compensation, in view of the importance of their role.

The Panel discussion initially focused on whether a review of the scientific quality of the intramural program as a whole would serve as an adequate evaluation of the scientific director. The Panel recognized that the best work accomplished in the institutes was of superb quality but disagreed with the idea that program quality as a whole could serve as the sole measure of performance.

There was extensive discussion about the dual roles performed by many of the scientific directors; namely, maintaining an active laboratory conducting scientific research and providing administrative leadership and intellectual stimulus for the intramural program. The first role is measured by the quality of the

individual's scientific accomplishments, and the second is measured by the scientific quality of the intramural program as a whole.

The Panel felt that for those scientific directors directly involved in continuing research, there should be a strict separation of the scientific evaluation from the administrative evaluation and that a scientific review by the board of scientific counselors should occur on the same 4-year cycle with the other scientists in the program.

With regard to evaluating the administrative duties, the Panel recognized that the scientific director is subject to an annual review through the Federal performance evaluation system. However, the Panel strongly felt that the board of scientific counselors, as an external body, should assess how well the intramural program is administered and what effect that administration has on the overall quality of the research program.

Issues Related to Strengthening the Intramural Scientific Review Process

In the course of its deliberations, the Panel addressed several additional issues related to those raised by the NAS/IOM report. The Panel examined the procedures for selecting reviewers and the mechanisms for ensuring that there is an appropriate response to the review. The Consultant Panel was concerned about negative perceptions of the review procedures, particularly those that called into question the accountability and independence of the intramural review process. Among the issues addressed by the Panel, with the goal of strengthening the review process, were the following:

- How should counselors be selected, and what are the appropriate size and length of service for the boards of scientific counselors?
- Is there a need for a set of minimum codified standards that would apply across all the institutes?
- What is the nature of the orientation received by counselors?
- How should the review be structured, to whom should the report of the review be delivered, and what should be the mechanisms for following through?
- What is the most appropriate mechanism for responding to the report of the review by the boards of scientific counselors?

Boards of Scientific Counselors

The Panel concurred with findings in the NAS/IOM report that the nomination of scientific counselors by the scientific director whose program is to be reviewed contributed to perceptions of conflict of interest. The Panel believed the nominating individual should be the chairperson of the board of scientific counselors

with the advice of the scientific director. The list of nominees should be provided by the chairperson to the director of the institute and the Deputy Director for Intramural Research, NIH, for approval. The appointment authority, with the exception of NCI, should remain with the Director, NIH. Ad hoc reviewers used for specific site visits also should be selected by the board chairperson with the scientific director's advice.

Concern was expressed by the Panel that in a 4-year term of office, no single scientific counselor would have the opportunity to review any laboratory more than once. The Panel believed the review process would be enhanced if a portion of the board had some prior experience reviewing a particular laboratory and felt continuity could be accomplished by lengthening the term of appointment for scientific counselors to 5 years.

It also was thought that continuity would be enhanced by increasing the size of the boards. This discussion centered on the most appropriate size of a board, the limited number of experts available for specific disciplines, the difficulty in recruiting them, and the NIH restrictions that prohibit individuals from serving on more than one board. Despite the recruitment difficulties, the panel strongly believed that the institutes should, to the extent possible, increase the number of individuals serving on their boards of scientific counselors.

The Panel considered how board members could make a meaningful contribution to the review process at the end of their appointments. The Panel believed it would be worthwhile to conduct exit surveys of the board members on issues of program quality and the efficacy of the review process. This survey was envisioned as a standard form that the departing members could complete after their last meeting and return to the chairperson, who would subsequently distribute them to sitting board members.

Review Function and Process

The question of uniformity of review procedures among the institutes was the focus of a concerted discussion by the Panel. Although they acknowledged that differences exist among the institutes that require variations in procedures, the Panel members felt that a minimum set of uniform standards should be developed and codified. The guidance found in Chapter 3005 together with the recommendations of the panel for strengthening the review process could serve as a basis for these standards.

The Panel believed that the Deputy Director for Intramural Research, NIH, should evaluate the institutes' unique procedures to ensure that the uniform requirements of NIH are met and communicate the experiences of the different processes to all of the scientific directors. The Deputy Director for Intramural Research, NIH, should also publish orientation guidelines for the scientific counselors that describe the uniform standards, the goals of the review process, and the responsibilities of the counselors. These guidelines should be provided to counselors as part of their briefing materials.

Panel members deliberated on the nature of the review and the areas of the program for which advice should be sought from the boards. The Panel believed that the boards of scientific counselors should provide advice on science, specific projects including new areas of development, tenure and promotion decisions, resource allocation, and other administrative matters.

The followup to the scientific review process was of particular interest to the Panel, and its deliberations focused on mechanisms designed to facilitate meaningful exchange between boards of scientific counselors and their respective institutes' intramural programs. Although the Panel believed that the board should provide an oral summary of its review before adjourning, the consultants thought it imperative that the briefing be attended by both institute director and scientific director, as well as by the Deputy Director for Intramural Research, NIH.

The Consultant Panel also considered the impact of timing during the review cycle and felt that within a month of adjournment, the board should provide a final written report of its review to the scientific director. Within 6 months of receiving the report, but before the next board meeting, the scientific director should respond to the board's report indicating any areas of agreement and disagreement and the changes that will be undertaken. Also at this time, a copy of the board report and the scientific director's response to it should be sent to the institute director; the national advisory council; the NIH Deputy Director for Intramural Research; and the Director, NIH.

No later than 1 year after the review, a written response should be provided to the board of scientific counselors by the scientific director, summarizing the results of any actions taken.

Finally, the Panel clearly reaffirmed the mandated oversight role of the national advisory councils. The Panel concluded that the institute's advisory council should review the intramural research program at least once a year and that it should be provided, at a minimum, with the report of the board of scientific counselors and the written response of the scientific director.

Summary of Recommendations

Monitoring of the Intramural Research Program

1. An ad hoc Consultant Panel of the DAC should be convened in 2 years, and periodically thereafter, to review progress on the following recommendations and changes in the intramural scientific review process.

Evaluation of the Scientific Director

2. The scientific and administrative performance of the scientific directors should be evaluated every 4 years by the boards of scientific counselors. The chairperson of the board of scientific counselors should provide the institute director with a written evaluation of the scientific director, including a discussion of the overall direction of the intramural program and the efficacy of the review process. The institute director may request an evaluation of the scientific director by the chairperson each year.

Boards of Scientific Counselors

3. Nominations for the board of scientific counselors should be provided to the director of the institute by the chairman of the board of scientific counselors with the advice of the scientific director. The institute director and the Deputy Director for Intramural Research, NIH, should provide a final review and approval of the list of nominees. The appointment authority, with the exception of NCI, should remain with the Director, NIH. Ad hoc reviewers should be selected by the chairperson of the board of scientific counselors with the advice of the scientific director.
4. The term of office for scientific counselors should be increased to 5 years to facilitate continuity of review and to allow the review of specific programs more than once by the same counselor(s).
5. The institutes should, to the extent possible, increase the number of individuals serving on their boards of scientific counselors.
6. Upon completion of their appointment, scientific counselors should be surveyed by the chairperson of the board of scientific counselors on issues of program quality and the scientific review process. This survey information should be provided to current board members.

Review Function and Process

7. Uniform standards for scientific review procedures should be developed and codified.
8. Within certain specific requirements, each institute should be allowed to develop its own procedures for the organization and structure of the scientific review meetings. The Deputy Director for Intramural Research, NIH, should

evaluate the institutes' procedures to ensure that the uniform requirements of NIH are met and to communicate the experiences of the different processes to all of the scientific directors.

9. Scientific counselors should be provided with orientation guidelines that describe the review procedures, the goals of the process, and the responsibilities of counselors. These guidelines should be published by the Deputy Director of Intramural Research, NIH.
10. The boards of scientific counselors should provide evaluation and advice on science, specific projects (including new areas of development), tenure and promotion decisions, resource allocation, and other administrative matters.
11. All board members should be provided with a summary of the organization of the laboratory to be reviewed; the various sections; all personnel, space usage, operating budget, and outside contracts; and Cooperative Research and Development Agreements. Each scientist being reviewed should supply details of ongoing work, a curriculum vitae, reprints of the three to five most important recent publications, and an analysis of the amount of support staff and space that scientist uses.
12. Before the board adjourns, an oral summary of the review should be presented to the scientific director; the institute director; and the Deputy Director for Intramural Research, NIH; or their designees.
13. Within a month of adjournment, the board should provide a written report of its review to the scientific director. Those portions of the report that pertain to particular laboratory/branch chiefs should be provided to them by the scientific director. The scientific director and the laboratory/branch chief should discuss the evaluations and recommendations in the report. The scientific director may also choose to discuss appropriate parts of the report with section chiefs and individual scientists who have been reviewed.
14. Within 6 months of receiving the board's report, but before the next board of scientific counselors' meeting, the scientific director should respond to the board indicating areas of agreement and disagreement and any possible changes that may be undertaken. A copy of the report and the response of the scientific director should be sent to the director of the institute; the Deputy Director for Intramural Research, NIH; the Director, NIH; and the institute's national advisory council.
15. No later than 1 year after the review, a written response should be provided to the board of scientific counselors by the scientific director, summarizing the results of any actions taken.
16. The institute's national advisory council should be provided an overview of the institute's intramural research program at least once a year. The overview should include, at a minimum, a discussion of the board of scientific counselors' report and the response of the scientific director.

Conclusion

This study and the Consultant Panel's recommendations for strengthening the NIH intramural scientific review procedures are in response to the recent review of the NIH intramural program by NAS/IOM.

In its report, the NAS/IOM study committee expressed concerns about whether the review process was sufficient to sustain the future excellence of the intramural program at NIH. The study committee felt that the mechanics of the review process itself were sound, but it framed the issue in terms of what changes could be made to demonstrate that tough questions about the review process were being asked. Concerns about the appointment process for scientific counselors and the procedures for following through on reports by boards of scientific counselors also were expressed by the study committee.

The NAS/IOM solutions to these issues included an enhanced monitoring role for the DAC, and the requirement that the scientific directors and their intramural programs be reviewed by an external body every 4 years.

The Panel concurs with the NAS/IOM study committee's findings that measures should be taken to strengthen the scientific review process and especially applauds its recognition of the special contributions of the scientific directors to the excellence of the intramural research programs.

Since its inception, the DAC has served an advisory capacity on broad science policy matters pertinent to the NIH mission, and the Consultant Panel believes it is appropriate for the DAC to examine and provide its advice periodically on the scientific review procedures of the intramural research program. However, the Panel does not believe that the DAC is the most appropriate body for *monitoring* the review process and has instead sought to strengthen the existing system.

The strengthening of the process should occur through the implementation of the Consultant Panel's recommendations. The recommendations provide specific means for strengthening the boards of scientific counselors, a more rigorous review and response process based on codified standards, and a more impartial counselor selection process. Finally, the Panel recommends procedures for the periodic review of the scientific and administrative performance of the scientific directors.

APPENDIX A

Excerpts from NAS/IOM Report
*A Healthy NIH Intramural Program:
Structural Change or
Administrative Remedies?*

Appendix A

Relevant Excerpts from the NAS/IOM Report

A Healthy NIH Intramural Program: Structural Change or Administrative Remedies?

NOTE

References to the scientific review of the NIH intramural research program have been excerpted from pages 4, 5, 8, 9, 41, 42, 43, 138 and 139 of the National Academy of Sciences, Institute of Medicine report, *A Healthy NIH Intramural Program: Structural Change or Administrative Remedies?* Copies of the report are available from the Office of Intramural Affairs, NIH.

INSTITUTE OF MEDICINE

REPORT OF A STUDY

A Healthy NIH Intramural Program

Structural Change or
Administrative Remedies?

1988



Quality of the Intramural Program

The committee believes that unless the quality of research in the intramural program is excellent, the investment of the government is not justified. The problems of measuring quality of scientific institutions are well known. The committee used several indicators of quality, such as citation analysis and a review of notable achievements. It also examined quality assurance mechanisms. These indicators suggest that no serious decline in quality has occurred in one of our nation's most important centers of biomedical research.

One can identify many investigators who are among the most respected in their fields. However, not all work in the intramural program meets the same high standards. This variability perhaps is to be expected in any research organization of the size and scope of the intramural program. The committee was unable to determine the extent to which notable scientists mask a cadre of less productive scientists. Nevertheless, it is the committee's judgment that further improvements in the quality of the program are essential and attainable.

There has been long-standing concern in the biomedical community that the review process for the intramural research program lacks the rigor of the competitive peer review process of the extramural program. Although in recent years NIH has taken action to improve this process, inadequacies remain in the appointment process and the degree to which recommendations of the Board of Scientific Counselors are given serious consideration. The committee believes it is particularly important that accountability to a disinterested body, external to the intramural program and institutes, has oversight responsibility to ensure the integrity of the review process. The committee does not recommend that the intramural program adopt the procedures by which the extramural competitive grants are evaluated. But, a more credible and independent peer review system--suitable for the environment--is essential to sustain the future vitality of the intramural program. This is a key step in ensuring the most effective use of the resources invested in the program.

A rigorous review process is necessary but not sufficient to sustain quality. Under the leadership of the institute director, the scientific director of each institute is key to the success of the intramural program, providing both intellectual and administrative leadership. Not only do scientific directors control resources, but, less tangibly, they are responsible for the spirit and morale of the institute.

The committee believes that the qualities of demonstrated scientific achievement, leadership, and administrative ability that are needed for this position are rare commodities. To attract people of sufficient stature requires that a premium be paid.

(From pp. 8-9)

Improving the Review of the Intramural Program

Several of the committee's recommendations are designed to maintain high scientific standards. Recommendations to give NIH managers the necessary flexibility to compete for personnel and provide a productive work environment are clearly intended to enhance the intellectual capital of the program. The committee believes, however, that disinterested review of the intramural research programs and assurance of implementation of reasonable recommendations also is essential to credible quality assurance.

Two recommendations address the review and resource allocation process. A panel chaired by a member of the NIH Director's Advisory Committee should be established to monitor the intramural research program review. The functions of this panel would be to oversee the integrity of the process, while taking care not to replicate the activities of the Boards of Scientific Counselors. Rather, its oversight should focus on areas that are most vulnerable to criticism, namely the selection of the reviewers and the appropriate response to recommendations.

Each of the scientific directors and their intramural programs should be reviewed as a whole every four years by an external group. The review report should be submitted to the director of the relevant institute, the NIH Deputy Director for Intramural Research, the Director of NIH, and the Director's Advisory Committee. The committee believes such a review to be necessary because of the importance of ensuring the vitality of the intramural program. The intent of the periodic review is not to limit arbitrarily the term of the scientific director, but rather to put in place a process that will ensure vigorous leadership. The responsibility of the scientific director requires having the scientific vision needed to allocate intramural resources productively, as well as function as a highly skilled manager. To recruit and retain scientists with this extraordinary set of attributes, the committee recommends that those holding the position of scientific director receive additional compensation. This will become possible under the recommended personnel demonstration program.

(From pp. 41-43)

Review of Intramural Laboratories

NIH policy states that "all research conducted intramurally must be reviewed regularly by highly qualified outside scientists." For this purpose, each institute appoints a board of scientific counselors to review the intramural work of each institute. The boards are composed of scientists with outstanding achievements and expertise in the fields under review. The institute's scientific director may invite additional experts to supplement the expertise of the board members for specific reviews.

Nominations for board membership are made by scientific directors and are approved by the Deputy Director of NIH and the individual institute director. Members are appointed by the Director of NIH. During these reviews, the board

of scientific counselors considers the quality of research accomplished since the last review and its contribution to the institute's mission. Over a period of time, each laboratory and tenured principal investigator is examined, as are scientists being considered for tenured positions. The board offers advice to the scientific director regarding allocation of personnel positions, funding of specific research areas, and future directions for research.

Prior to the review, members of the board of scientific counselors receive written descriptions of the laboratories' research, staff qualifications, budget summaries, space allocations, and research support contracts. When the board meets, tenured scientists and junior staff report on present and planned research--board members have an opportunity to question the scientists and to visit laboratories.

Within four months of review, a report of the board's findings and recommendations is submitted for information to the scientific director, the director of the institute, the NIH Deputy Director for Intramural Research, and the Director of NIH. Following review by the boards of scientific directors of all the institutes, the report is sent to each institute's national advisory council for information and comment. The scientific director is required to report to the board of scientific counselors, at the earliest practical date, on actions taken on their recommendations (Eberhart, 1982; National Institutes of Health, 1986a).

Feedback to the board of scientific counselors was of particular concern to members of the 1984 Institute of Medicine's Panel to Study the Current Organizational Structure of the NIH (Institute of Medicine, 1984), who interviewed members of the Boards. Many board members expressed a desire to be better informed regarding the institutes' implementation of their recommendations, suggesting that their recommendations were not always given serious consideration.

In 1985, the Director of NIH recruited a group of external reviewers to examine the management of the Clinical Center. As part of the review, 8 experts from a broad spectrum of clinical disciplines evaluated 50 current or recently completed protocols selected by the director and deputy director of the Clinical Center. These protocols were chosen to represent "high quality" examples of research that made intensive use of the Clinical Center resources. The reviewers concluded:

There was substantial variation in the quality of the protocols reviewed, from truly outstanding to quite poor, and there was also considerable variation of quality in and among the Institutes....

The reviewers noted differences in the scientific merit review mechanisms among the Institutes and commented on the need for a more rigorous review mechanism in those Institutes where the protocols were weak (National Institutes of Health, 1985).

At about this time, Congress became concerned about the intramural review process in the context of deliberating on the 1985 Health Research Extension Act. The conference committee report notes the following:

The conference agreement requires the Director of NIH to establish procedures for periodic technical and scientific peer review of all intramural research conducted at the National Institutes of Health. It is not the conferees' intent that the review procedures for intramural research be the same as those for extramural research....

An entity conducting peer review of intramural research is to provide the institute's advisory council with a written description of the research, the results of the review and the recommendations of the reviewing entity. The conference agreement authorizes, but does not require, the advisory council to make recommendations to the institute director regarding intramural activities conducted by the institute (Health Research Extension Act, 1985).

As a result of congressional concern, the review process has been tightened. The recommendations of the boards of scientific counselors must be answered in writing by the scientific director of the institute at the next meeting of the board (National Institutes of Health, 1986b).

The committee commends NIH for its actions to strengthen the review procedures. It has, however, identified two specific points in the review system that lack mechanisms to ensure objectivity and accountability. First, while few question the stature of those who serve on boards of scientific counselors and as ad hoc consultants, the fact that they are nominated by the scientific director of the institute whose program will be under review compromises the external credibility of their report. Second, despite improved feedback to the board of scientific counselors on the implementation of their recommendations, the scientific director is at no time accountable to anyone outside the institute. Because this process is so often unfavorably compared with the rigorous extramural peer review--particularly by some who believe that intramural funds would be better spent for unfunded extramural projects--it is important that the system has real and visible safeguards.

A rigorous review process is necessary but not sufficient to sustain quality. The scientific director of each institute is key to the success of the research program, providing both intellectual and administrative leadership. Not only do the scientific directors control resources, but, less tangibly, they are responsible for the scientific esprit of the institute. Subsequent chapters include discussion of the problems of recruiting and retaining outstanding individuals for these jobs.

(From pp. 138-139)

Assuring Quality. The committee has four major recommendations designed to assure that the quality of the intramural program be maintained at a high level for the future. The first three relate to assuring that the review process can be seen to be rigorous and leads to wise use of intramural resources. The last recommends a program to make NIH competitive for a share of the most promising young investigators in the country.

The Review Process. To improve the external validity of the review process, the committee recommends that a panel chaired by a member of the Director's Advisory Committee should be established to monitor the intramural research program review. The functions of this panel would be to monitor the integrity of the process, while taking care not to replicate the activities of the boards of scientific counselors. Its oversight should focus on areas that are most vulnerable to criticism, namely the selection of the reviewers and the implementation of recommendations.

Each of the scientific directors and their intramural programs should be reviewed as a whole every four years by an external group. The review report should be submitted to the director of the relevant institute, the NIH Deputy Director for Intramural Research, the Director of NIH, and the Director's Advisory Committee. The committee believes that such a review is necessary because of the importance of ensuring the vitality of the intramural program. The intent of the periodic review is not to limit arbitrarily the term of the scientific director, but rather, to put in place a process that will ensure vigorous leadership. Under the general leadership of the institute director, and with the advice of the Board of Scientific Counselors, the scientific director exercises a decisive role in influencing the intramural program. The right person in this position functions not merely as a caretaker, but a force for excellence. The responsibility of the scientific director requires that he/she have the scientific vision needed to allocate intramural resources productively, as well as to function as a highly skilled manager. Therefore, the committee recommends that those holding the position of scientific director receive additional compensation. This will become possible under the recommended personnel demonstration program.

APPENDIX B
September 5, 1989
Meeting Agenda

Appendix B

Agenda

Strengthening the Scientific Review Procedures of the NIH Intramural Research Program

Tuesday, September 5, 1989

Building 31, Conference Room 9
National Institutes of Health
Bethesda, Maryland

- 8:30 Opening Remarks Dr. Hill
- 8:40 Statement of the Issue Dr. Petersdorf
- Discussion
- 9:10 Summary Overview of Current NIH Intramural
Scientific Review Procedures Dr. Rall
- 9:30 Current Intramural Scientific Review Procedures
at the National Institute on Allergy and
Infectious Diseases Dr. Gallin
- 9:50 Current Intramural Scientific Review Procedures
at the National Institute of Child Health and Human
Development Dr. Levine
- 10:10 Current Intramural Scientific Review Procedures
at the National Cancer Institute Dr. Rabson
- 10:30 Break
- 10:45 Working Paper on Proposed NIH Intramural
Scientific Review Procedures Dr. Korn
- Discussion
- 12:15 Lunch

1:15 Discussion, Report Formulation and
Recommendations Session Consultant Panel

3:00 Break

3:15 Resume Panel Session

4:45 Closing Remarks Dr. Hill

5:00 Adjournment

APPENDIX C

List of Presenters

Appendix C

List of Presenters

Strengthening the Scientific Review Procedures of the NIH Intramural Research Program

Tuesday, September 5, 1989

John I. Gallin, M.D.
Director
Intramural Research Program
National Institute of Allergy and
Infectious Diseases

Arthur S. Levine, M.D.
Director
Intramural Research Program
National Institute of Child Health
and Human Development

Edward D. Korn, Ph.D.
Director
Division of Intramural Research
National Heart, Lung, and Blood
Institute

Robert G. Petersdorf, M.D.
President
Association of American
Medical Colleges

Alan Rabson, M.D.
Director
Division of Cancer Biology and
Diagnosis
National Cancer Institute

Edward E. Rall, M.D., Ph.D.
Deputy Director for Intramural
Research
Office of the Director
National Institutes of Health

APPENDIX D
DHHS Manual Transmittal Sheet,
Chapter 3005
Review and Evaluation of
Intramural Research by
Boards of Scientific Counselors

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

RELEASE DATE

8/4/86

MANUAL TRANSMITTAL SHEET

SUBJECT

3005 REVIEW AND EVALUATION OF INTRAMURAL RESEARCH
BY BOARDS OF SCIENTIFIC COUNSELORS

1. Explanation of Material Transmitted: This chapter establishes policy and procedures for outside review and evaluation of intramural research at NIH by Boards of Scientific Counselors. It modifies Manual Chapter 3005, issued 3/4/85, to include provisions of Public Law 99-158.
2. Material Superseded: Previous NIH Manual Chapter 3005, dated 3/4/85.
3. Filing Instructions:

Remove

3005 dated 3/4/85

Insert

3005 dated 8/4/86

Distribution

F-401 and F-405

3005 REVIEW AND EVALUATION OF INTRAMURAL RESEARCH
BY BOARDS OF SCIENTIFIC COUNSELORS

- A. Purpose This chapter establishes policy and procedures for outside scientific review and evaluation of intramural research at NIH by Boards of Scientific Counselors.
- B. Background Intramural research at NIH has been reviewed by committees of scientists from outside the NIH since 1956. In that year the first committees, called Boards of Scientific Counselors, were appointed to review intramural research in the individual Institutes. Board procedures have evolved over the years. On March 4, 1985, the original version of this Manual Chapter was issued to establish policy and procedures for the evaluation of intramural research by the Boards. Subsequently, on November 20, 1985, Public Law 99-158, the Health Research Extension Act of 1985 was enacted, including a provision making mandatory what was then standard policy on review of intramural research. This present chapter is a revision of the March 4, 1985 Chapter; it makes explicit the present law concerning intramural research review. It repeats the provisions of the earlier Chapter, none of which was changed by Public Law 99-158.
- C. References
1. Section 301 of the PHS Act authorizes the conduct of research, investigations, experiments, demonstrations and studies relating to diseases and impairments of man.
 2. Sections 402(b)(3), 406(a)(3) and 492(b) of the Public Health Service Act, as amended by Section 2 of Public Law 99-158.
 3. Memorandum of July 18, 1980, from Dr. Robert Goldberger, Deputy Director for Science, entitled "Modus Operandi of Boards of Scientific Counselors."
 4. Report by Dr. John C. Eberhart, dated November 3, 1982, entitled "Review and Evaluation of Intramural Research."
 5. NIH Public Advisory Groups, October 1985.
 6. The NIH Committee Management Handbook contains instructions and sample notices concerning the meetings of Boards of Scientific Counselors. (To be issued.)
- D. Definitions
1. Boards of Scientific Counselors.
Public advisory committees, established under provisions of the Federal Advisory Committee Act (Public Law 92-463) which

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BY BOARDS OF SCIENTIFIC COUNSELORS

review, discuss, and evaluate research projects and programs conducted by the NIH, and by ADAMHA intramural programs located on the NIH campus. The reviews include evaluation of the work of individual scientists as well as of the quality of the research itself.

2. Outside review.

The review of NIH research and of staff scientists by highly qualified scientists from outside the NIH who are formally appointed to a public advisory committee called a Board of Scientific Counselors. This process is referred to in the law as "technical and scientific peer review."

- E. Policy It is the policy of the National Institutes of Health (and of ADAMHA Institutes with intramural components at NIH) that all research conducted intramurally must be reviewed regularly by highly qualified outside scientists. The review will include the quality of the research and the accomplishments of individual scientists. Scientists within Institutes will be reviewed by their established Boards of Scientific Counselors. Scientists within service Divisions (Clinical Center, Division of Computer Research and Technology, Division of Research Services) will be reviewed either by the Board of Scientific Counselors of a collaborating investigator or by an ad hoc committee consisting of outside reviewers and Institute scientists. The composition of a given ad hoc committee will be determined by the Division Director in consultation with the Deputy Director for Intramural Research. These Committees will function as Boards of Scientific Counselors and will follow the same procedures in carrying out their reviews.

This policy is reinforced by Section 492(b) of the PHS Act:

"The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that--

- (1) the reviewing entity be provided a written description of the research to be reviewed, and
- (2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3)."

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These reviews and any resulting recommendations should be included in a written report submitted to the Scientific Director, who will transmit it to the BID Director, the Deputy Director for Intramural Research, and the Director, NIH. In addition, as required by PHS Act Section 492(b) above, the Institute will provide to its National Advisory Council written descriptions of the research reviewed by the Board of Scientific Counselors, and the results of that review. Such communications should be made to the Council at least annually. As stated in PHS Act Section 406(a)(3)(A)(i), the Advisory Council "may on the basis of the materials provided under Section 492(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research."

F. Procedures

1. Composition of Boards Every effort shall be made to maintain the full complement of Board members. A primary consideration of scientific qualification for Board membership shall be international recognition as an authority in the fields under review. Each Board should exhibit reasonable balance in membership with respect to gender, race, and geographical distribution of members' institutions. A board may make use of ad hoc consultants when the Scientific Director deems it necessary. Board members are nominated by the BID Scientific Director and, with the exception of the NCI, approved by the BID Director and the Deputy Director for Intramural Research, and appointed by the Director, NIH. Under the PHS Act, Sec. 413(b)(7), the Director, NCI, has authority, in consultation with the National Cancer Advisory Board, to appoint members of NCI Boards of Scientific Counselors.
2. Frequency of Review Meetings The Boards of Scientific Counselors shall meet often enough (ordinarily two or three times each year) to assure that the work of each intramural scientist on a permanent appointment in each Laboratory or Branch is reviewed at least once every four years.
3. Information Supplied to Boards of Scientific Counselors Prior to Meeting The following information shall be provided to each Board reviewer in advance of the meeting.

For each Laboratory/Branch being reviewed:

- (a) A staff list of all employees to include name, occupational specialty, type of appointment and grade.

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BY BOARDS OF SCIENTIFIC COUNSELORS

- (b) A list of all contracts which support the work of the Laboratory/Branch.

For each scientist whose work is to be reviewed:

- (c) A current CV and Bibliography and recent relevant reprints.
- (d) A succinct summary of current research and statement of future plans.
- (e) The amount of technical and postdoctoral support.

A copy of the last Board of Scientific Counselors review of the Laboratory/Branch should be available to the Board. The Conference Report for this section of the PHS Act notes that "the written description should present the overall past accomplishments of the laboratory and its investigators since the last review was conducted. The written description might also present: the general aims, objectives and projected directions of the research projects to be conducted; appropriate background information on possible future research projects; a brief summary of the general research plan; and an indication of the importance of the research projects."

4. Who is to be Reviewed Every independent intramural scientist on a permanent appointment must be reviewed and evaluated. In general, advice of the Board of Scientific Counselors also should be obtained concerning scientists who are being considered for conversion to tenure. The Scientific Director may, in addition, choose to ask the Board to review the work of other staff scientists. Over time, the active program of each laboratory or other intramural research unit is to be reviewed.
5. Review Format Organization and structure of meetings of the Board of Scientific Counselors will be left to the discretion of the Scientific Director. Review formats found to be useful in the past include: (a) oral presentations by scientists to a plenary session of the Board, (b) individual interviews of scientists by Board members or consultants, and (c) small group interviews by one or more Board members or consultants with members of a Section, Unit or working group. The reviewers should be given an opportunity to visit the facilities where the research is carried out, if they wish.

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6. Reporting of Results of Reviews

- (a) The report of the Board of Scientific Counselors is to be a narrative critique from the Chair of the Board, following the outline preferred by the Scientific Director.
- (b) Evaluations of individual investigators must address, at a minimum, the following questions: are good questions being asked, are appropriate approaches being used to obtain answers, and are the resources available to this scientist appropriate to the accomplishments to date? These evaluations should be written by members of the Board of Scientific Counselors or consultants, and should reflect the collective views of the total Board (or at least a majority).
- (c) The total report is to be sent within four months of the review to the Scientific Director, who is responsible for transmitting it to the BID Director, the Deputy Director for Intramural Research, and the Director, NIH. The Office of Intramural Affairs will distribute copies to the Board of Scientific Directors and schedule its discussion by all members of that group.
- (d) At least annually each Institute will transmit to its national advisory council descriptions of the research that has been reviewed by its Board(s) of Scientific Counselors during the preceding year, together with the results of the reviews. Consideration shall be given to providing the items listed under section F3 in this Chapter. The results of the reviews and Board recommendations may be communicated to the Council orally, by the Scientific Director or the Chair of the Board of Scientific Counselors, or in writing. If in writing, the evaluations of individual scientists may, for privacy reasons, be omitted.

7. Followup It is the responsibility of the Scientific Director to report back to the Board of Scientific Counselors the action taken in response to recommendations made by the Board. This report shall describe actions taken or explain why it was found impossible or inadvisable to follow the recommendations.

8. Schedule of Reviews Each Scientific Director must submit to the Deputy Director for Intramural Research a schedule of the proposed dates of review of each Laboratory/Branch in the

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Institute or Division covering the next four-year review cycle. This schedule must be updated annually and submitted to the Deputy Director for Intramural Research by September 1 of each year.

- G. Additional Information For more information on this chapter, contact the Office of Intramural Affairs on 496-3561.
- H. Additional Copies of this Chapter For extra copies of this chapter send a Form NIH 414-5 to the Printing and Reproduction Branch, Division of Technical Services, Building 31, Room 3C02.

APPENDIX E

*Working Paper for the Advisory Panel
Evaluating the Review Process of NIH
Intramural Programs*

August 1, 1989

WORKING PAPER FOR THE NIH DIRECTOR'S SUBCOMMITTEE
EVALUATING THE REVIEW PROCESS OF NIH INTRAMURAL PROGRAMS

I. INTRODUCTION

The Director, NIH has strongly endorsed the emphasis given in the recent IOM Report on the NIH Intramural Program for (a) a sound external review of intramural NIH research, (b) the responsiveness of intramural NIH to such reviews, and (c) review of the performance of the Scientific Directors. To assure these goals are met, the ad hoc subcommittee was established by the Director, NIH to evaluate the existing procedures for review of the Intramural Programs and to recommend procedures for (a) periodic review of the Scientific Directors, (b) mechanisms for selection of the members of the Boards of Scientific Counselors, and (c) implementation and follow-up to the Boards' recommendations. This working paper, prepared by representatives of the Intramural Community of NIH, provides a set of recommendations which modifies the current procedures to establish a uniform, rigorous review process of all of the Intramural Programs that will reinforce the existing high standards of excellence while preserving the unique features of the various Intramural Programs.

II. INTRAMURAL NIH AND THE ROLE OF THE BOARDS OF SCIENTIFIC COUNSELORS

The unique aspects of Intramural NIH derive, on the one hand, from its unprecedented stability of its research funding and support infrastructure, and, on the other hand, from the flexibility that derives from its administrative structure. The stability of funding has produced a large and highly varied complex of research programs, encompassing all of the biomedical disciplines, that can undertake long-term, high-risk investigations. The flexibility of management, together with the scope and excellence of its scientific programs, allows Intramural NIH to respond to national health emergencies with speed and efficiency, as exemplified by the discovery of the etiologic agent for AIDS and development of AZT for its treatment.

General management of each Intramural Program is by a Scientific Director, who is responsible to the Institute Director and who also interacts closely with the Deputy Director for Intramural Research, NIH, and the Scientific Directors of the other Institutes. Each Intramural Program comprises a number of Laboratories and Branches, each with a responsible Chief, and most Laboratories and Branches are sub-divided with Sections, each with a responsible Head and one or more independent investigators who direct the research of post-doctoral fellows and support staff.

While the Institute Director is ultimately responsible for the quality of the Intramural Program, the Scientific Director has the direct and immediate managerial and program responsibilities and also serves an important advisory role to the Institute Director on matters of science policy. The Scientific

Director must direct the scientific program within the constraints of the Civil Service and Public Health Service personnel systems, and with relatively fixed allotments of space, personnel and budget. Although the relative constancy of resources establishes a desirable stability, the restrictions on resources also demand a high degree of creativity of the Scientific Director to foster exciting, innovative research programs within the federal system.

The performances of the independent investigators are subject to virtually daily review by the Laboratory/Branch Chiefs and both the independent investigators and the Laboratory/Branch Chiefs are under continual review by the Scientific Director who meets frequently with the Institute Director. In addition, all conversions to tenure and promotions of the scientific staff within any one Institute must be approved by the NIH Board of Scientific Directors of all of the Institutes. The latter provides a measure of external peer evaluation of the Intramural Program of each Institute by the Scientific Directors of the other Institutes and the Deputy Director for Intramural Research, NIH, who chairs the NIH Board of Scientific Directors. Nonetheless, despite this extensive internal review of each Intramural Program, it is essential that the Intramural Programs and their Scientific Directors receive regularly scheduled, formal scientific review, evaluation and advice by external Boards of Scientific Counselors.

The first important role of the Board of Scientific Counselors is to advise the Scientific Director through independent, critical reviews and assessments of the research objectives and accomplishments of the Laboratories and Branches and each of the independent investigators. The Board of Scientific Counselors has the responsibility of recommending both programmatic changes and changes in level of support for individual scientists, including conversions to tenure status and promotions. The Scientific Director must be responsive to the Board of Scientific Counselors by either implementing its recommendations or providing the reasons for not doing so.

The second important role of the Board of Scientific Counselors is to review and assess the performance of the Scientific Director. In large measure, the sum of the reviews of the Laboratories and Branches will provide a continuing review of the performance of the Scientific Director. In addition, at periodic intervals the Scientific Director will be specifically reviewed and a formal report made to the Institute Director.

III. COMPOSITION AND SELECTION OF THE BOARDS OF SCIENTIFIC COUNSELORS

The Board of Scientific Counselors should comprise 6-8 members each serving a 4-year term. The Board should have national distribution with balanced representation of women and minorities; the first requirement is that each member be an outstanding scientist. The Scientific Director, with the advice of the Chairperson of the Board of Scientific Counselors, will provide a provisional list of potential nominees to the Institute Director. The Institute Director will present the final list of nominees to the Deputy Director for Intramural Research, NIH, who will select and appoint the Counselors. This process will allow appropriate input from those most knowledgeable about the specific needs

of each Board while assuring that the actual selection and appointment is independent of the Institute. The Chairperson of the Board of Scientific Counselors will be selected by the Scientific Director with the advice of the Institute Director, usually from one of the members serving for a fourth year.

While the entire Board will be expected to participate in each of the review sessions, normally there will be too few Counselors with the specific expertise necessary to evaluate critically all of the investigators under review. Therefore, the Board will be supplemented for each review with ad hoc reviewers selected by the Chairperson of the Board with the advice of the Scientific Director.

IV. REVIEW OF THE INTRAMURAL PROGRAM

A. GENERAL FEATURES: The individual needs of each Institute are probably best served by different specific mechanisms of scientific review. Within certain specific requirements, therefore, each Institute should be allowed to develop its own procedures. The Deputy Director for Intramural Research, NIH, will evaluate the details of each Institute's procedures both to assure that the uniform requirements of the NIH are met and to communicate the experiences of the different processes to all of the Scientific Directors.

Scientific reviews by each Board of Scientific Counselors supplemented by ad hoc members must be held at least semi-annually. Each Laboratory and Branch must be reviewed at least once every four years. At a minimum, each tenured investigator of the Laboratory or Branch must be reviewed. The ad hoc reviewers will assure an impartial scientific review of each individual by national and international standards of excellence; the permanent Board members will be able to place the specific information into the general context of the Institute's program needs and resources.

B. MATERIAL TO BE PROVIDED TO THE REVIEWERS: For each scientist to be reviewed, the Board will be provided beforehand with a short, written summary of the presentation (emphasizing accomplishments since the last review and a precis of ongoing work, including a short statement of future plans), a curriculum vitae, a list of publications of the last 5 years, a few representative reprints, enumeration of support personnel (post-doctoral fellows, technicians, secretaries), and space assignment. The Laboratory/Branch Chief will provide a summary of the administrative organization of the Laboratory/Branch including its personnel, space allocations, budget information, and contract support and Cooperative Research and Development Agreements.

C. REVIEW PROCESS: Generally, the Laboratory/Branch Chief will present an overview of the research activities. The review of the individual scientists may take the form of oral presentations to the assembled Board, followed by discussion, or a mixture of oral presentations and separate interviews with one or more members of the Board and ad hoc reviewers. The Board will have Executive Sessions to discuss the merits of the individual presentations as well as broader aspects of the Intramural Program. The Board may wish to meet with the

Laboratory/Branch Chiefs to clarify its understanding of the scientific presentations and provide the Laboratory/Branch Chief an opportunity to respond to its questions before the written report is prepared. Before the Board adjourns, an oral summary will be presented to the Scientific Director. The Institute Director and the Deputy Director for Intramural Research, NIH, or their designees will be invited to these sessions. The Board will provide a written Report to the Scientific Director within one month of the review.

D. RESPONSE TO THE REVIEW: The relevant portion of the Board's Report will be given to the Laboratory/Branch Chief by the Scientific Director, and the Scientific Director and Laboratory/Branch Chief will discuss the evaluations and recommendations in the Report. The Scientific Director may also wish to discuss the Report privately with one or more of the investigators under review. Within six months of the review, the Scientific Director will respond to the Board indicating areas of agreement and disagreement and any possible changes that may be undertaken. Within one year of the review, a written response will be provided to the Board by the Scientific Director summarizing the results of any actions taken.

E. DISPOSITION OF THE REVIEW: Within six months of the review, the Scientific Director will transmit the Board's Report and the Scientific Director's response to the Institute Director, the NIH Deputy Director For Intramural Research, and the Director, NIH. The Report will be distributed to the Scientific Directors of all of the Institutes and discussed at a regularly scheduled meeting of the NIH Board of Scientific Directors. In addition, the Scientific Director will annually present to the Institute's National Advisory Council the written material reviewed by the Board the previous year and the Board's Reports.

IV. REVIEW OF THE SCIENTIFIC DIRECTORS

The Board of Scientific Counselors is in the best position to provide the Institute Director, who has the ultimate responsibility for the quality of the Intramural Program, with external evaluations of the performances of the Scientific Director. From its continued interaction with the Intramural Program, the Board of Scientific Counselors is well informed on the goals and accomplishments of the intramural program. Indeed, evaluation of the performance of the Scientific Director is inherent in the aggregate of the reviews of the Laboratories and Branches of the Intramural Program, and in the Board's evaluation of the response of the Scientific Director to its recommendations. Therefore, once every four years the Chairperson of the Board of Scientific Counselors will provide a written report to the Institute Director evaluating the review process, the overall direction of the intramural program, and its major accomplishments. The Institute Director may request an evaluation of the Scientific Director by the Chairperson each year.

APPENDIX F

Review and Evaluation of NIH Intramural Research—1989

August 9, 1989

Review and Evaluation of Intramural Research - 1989

John C. Eberhart, Ph.D.
Office of Intramural Research

- A. In late 1988 the Institute of Medicine (IOM) Committee to Study Strategies to Strengthen the Scientific Excellence of the NIH Intramural Research Program released its report, A Healthy NIH Intramural Program: Structural Change or Administrative Remedies? Among other issues the Report commented on the "peer review" process by which boards of scientific counselors composed of outside scientists evaluate the intramural research programs of the institutes. The authors of the report write that "the committee has four major recommendations designed to assure that the quality of the intramural program be maintained at a high level for the future. The first three relate to assuring that the review process can be seen to be rigorous and leads to wise use of intramural resources. . ." Two of the three emphasize the importance of the scientific director in an intramural program, and recommend both that scientific directors should be paid more and that each one and his or her program "should be reviewed as a whole every four years by an external group." The third recommendation, intended to "improve the external validity of the review process," states "that a panel chaired by a member of the Director's Advisory Committee (DAC) should be established to monitor the intramural research program review." The report emphasizes that the "monitoring" should "take care not to replicate the activities of the boards of scientific counselors."

In response to these recommendations by the IOM Committee the Director of NIH has appointed a committee, chaired by a member of the DAC and including several former members of boards of scientific counselors, to review the evaluation process now in use in the NIH intramural programs and to make any recommendations they believe would improve it. To assist the work of this committee the present paper is intended to serve as a reasonably factual account of what now takes place in the process of intramural evaluation.

This report is thus a survey and analysis of intramural evaluation in 1989, and is, in a sense, an updating of the 1982 report by the writer on "Review and Evaluation in Intramural Research."

- B. "Evaluation" in intramural research and "peer review" of external grant applications.

One reason--perhaps the principal reason--for the IOM recommendations about the review of intramural research is the committee's view that, regardless of the dissimilarities of the intramural and extramural programs, external review of both should be, or appear to be, equally

critical, tough, objective, unbiased. This seems to reflect the feeling of some outside scientists who depend on NIH's extramural funding for support of their research that their research grant applications are reviewed more critically than are intramural's ongoing programs. Whether the IOM Committee believes that intramural reviews are actually less critical and objective, or that they merely appear that way, is not clear. It may not be relevant, since a widespread perception of soft evaluation for intramural scientists, whether true or not, would in the long run be destructive.

Nevertheless some comments are in order about NIH's two principal program segments.

Intramural research is a series of programs operated by 12 NIH institutes, 3 non-NIH institutes on the NIH campus, and 3 divisions and centers. The intramural programs are staffed by full-time salaried scientists plus a large number of non-salaried "guest" scientists. Some 4,845 scientists with M.D.s or Ph.D.s currently work in the intramural programs, of whom 3,843 are paid by NIH and 1,002 are guest researchers and volunteers. The research of this staff, plus the technical and support staff, is funded by an appropriation (in FY 1989) of \$692,272,000, which is 12 percent of the total NIH appropriation for research. The other 88 percent supports the extramural research program.

The extramural research program is a grant-in-aid and contract program providing support for research projects and programs proposed by scientists in universities and other research institutions. Its importance to the nation is incalculable, since it procures for the long-term effort to promote the nation's health the skill and ingenuity of accomplished scientists no matter where they may work. The extramural program embodies a set of principles which have characterized it since NIH research grants were first authorized 45 years ago: (a) the merit of proposed research should determine which applications receive support; (b) that merit can best be determined by independent experts brought in from outside the federal government; and (c) the relevance of proposed research to the missions of the NIH can be considered in making distinctions between proposals of apparent equal merit. Such judgments of merit must be made in order to decide how the money for research grants is to be spent. The judgments of merit, in other words, are a necessary tool in the dispensation of funds from the research grants appropriation. An alternative approach--to make lump sum grants to universities and other research institutions, from which the institutions would decide which scientists' work should be supported--has been rejected in the past by extramural scientists, who seemingly prefer that individual allocations of research funds should be made by the NIH.

The outside experts who judge research grant applications are grouped into "study sections" which meet two or three times a year, usually in Bethesda, to review, often, a hundred or more applications. The 20,000 or more applications received annually keep more than a hundred study

sections busy. This peer review process is a large scale enterprise, costly in staff and money, which is justified only because its judgments on merit are generally accepted as careful, informed, and reasonably objective, and it satisfies most applicants as to its fairness. It owes a very great deal to the hundreds of outside scientists who are willing to work so hard in evaluating projects.

The intramural program, to go back to it for a moment, contrasts sharply in structure and funding with the extramural program. Based on the well-founded assumption that an institution dedicated to research can organize and run a research program, NIH's several institutes, responsive to the expressed will of the Congress, have organized, staffed, supervised, and evaluated research programs that complement extramural research in the mission areas. To recruit and retain talented research staff the Institutes confer tenure on their best scientists, and operate their programs in such a way as to develop and enhance the competence of staff scientists, and to enable those who perform successfully to make careers in the intramural program. The Congress annually appropriates money for each Institute; so much for extramural (88 percent of the research funds), and the remainder (12 percent) for the intramural program. With the intramural appropriation the institute director and scientific director generally set up budgets for individual intramural laboratories and branches, and in many institutes laboratory and branch chiefs then establish budgets for sections and/or individual investigators. These allocations of funds and other resources (space and positions) are based on two things: the supervisors' (scientific directors' and laboratory chiefs') knowledge of the scientists and their accomplishments and potential, and (2) the evaluation of scientists and research units by boards of scientific counselors.

The fact that external review by boards has been a fact of intramural life for more than 30 years should not, however, obscure the fact that skillful management and direction by program leaders is the sine qua non of a successful operating program. A good program can put up with uncritical outside reviews; no program can be good without skillful and critical administration. Though the individual intramural scientists have a high degree of freedom in the selection and pursuit of problems, they are each part of a hierarchical organization headed by a scientific director and a laboratory chief. They are responsible to these as well as to their own research goals and scientific standards. Such an operating research program, in contrast to a program of grants-in-aid, does not need a prospective "peer review" system in order to function. Decisions on allocation of budgets are not based on written applications, as in a grants program, but on close career-long knowledge of a cadre of carefully chosen scientists. Though any judgment is potentially fallible, and honest men and women may disagree on research promise (hence the valuable correction provided by the boards of scientific counselors), there is no problem of allocating resources that the program leaders cannot handle. All decisions cannot be made by committees, or boards. If there is merit in a large in-house biomedical research program, and the IOM Report is just the latest outside review

to say there is, program leaders must have authority to make decisions that maximize the long-term effectiveness of the program. They are expert, full-time, and dedicated. Others might differ with their judgments, but one of the tasks of management is to manage, and make decisions, even if others might differ as to their wisdom. Research conducted by industry is managed (and that means continual evaluation) by company officers without periodic inspection by outside visitors, and research in privately endowed organizations is often done the same way. People, by themselves, can run programs. They can manufacture, mine, publish, broadcast, build bridges, heal the sick, write laws, and do research, often successfully. The NIH intramural programs are no less able to do this than other private and governmental organizations.

Why, then, did the NIH, under the leadership of Dr. James A. Shannon, invite outside experts 30 years ago to form boards of scientific counselors to review NIH's intramural research programs and advise the Institutes on high spots and weak spots, changes that might improve the programs, and provide counsel to scientific directors and laboratory chiefs? The boards, formed in 1956, were not regarded as analogues of the extramural study sections, but rather as a way of using the country's best scientific experts to help scientific directors guide their programs wisely. There was recognition also that such a system of outside scientific review would have value in public accountability for the program, a not inconsiderable contribution.

Finally, how does evaluation of intramural research relate to extramural peer review?

1. Extramural peer review is prospective review by study sections of research proposals from thousands of outside scientists. It is designed to select for funding the best of the proposals that are relevant to the missions of the institutes concerned.
2. Intramural research evaluation is two things: (a) a continual review of all intramural research by scientific directors and laboratory chiefs, done as part of their management responsibility for initiating, guiding, and overseeing a research program; and (b) a repetitive retrospective review of each institute's program by a board of scientific counselors, supplemented by ad hoc reviewers, to assess programs, critique performance of research staff, and recommend needed changes.

C. NIH regulations governing review of intramural research.

Since 1985, the process by which boards of scientific counselors review and evaluate intramural research has been governed by Chapter 3005 in the NIH Manual. Until 1981, each Institute's board had developed its own method of review; in that year Dr. Robert Goldberger, Deputy Director for Science, issued a two-page set of minimum guidelines for board operations. The 1985 Manual Chapter, prepared after the 1982 Eberhart study of the boards, established a set of requirements that all boards were expected to meet. It was revised and reissued in 1986 after

Congress, in Public Law 99-158 (the Health Research Extension Act of 1985) added a few specifications. Because institute intramural programs and review boards conform to these requirements (and in a number of cases exceed them) it is worth summarizing what the Manual Chapter says.

1. NIH Manual 3005: Review and Evaluation of Intramural Research by Boards of Scientific Counselors.

It is NIH policy, as prescribed by the Director and stated in the chapter, that all intramural research shall be reviewed every four years or oftener by boards of scientific counselors. To facilitate such reviews members of the boards are to be provided with a variety of written material in advance of board meetings, to acquaint board members with the laboratory or branch being reviewed. Included are to be research summaries and future plans by the scientists to be reviewed, plus their CV's and bibliographies, staff lists, existing research contracts, and an agenda for the meeting. A copy of the last board report of the laboratory concerned is to be made available to the board. The work of all independent scientists in the laboratory is to be reviewed and evaluated, as are any younger scientists being considered for tenure.

The format of the meeting at which the review is to be carried out is left to the Scientific Director of the Institute, who works it out with his Board. The chapter states that "Review formats found to be useful in the past include; (a) oral presentations by scientists to a plenary session of the board, (b) individual interviews of scientists by board members or consultants, and (c) small group interviews by one or more board members or consultants with members of a section, unit, or working group." Board members may visit the laboratories if they wish.

The board chairman is responsible for writing the report summarizing and evaluating a laboratory's work. He is assisted by other board members and ad hoc consultants, who take responsibility for sections of the report. The final report is to be sent within four months of the review to the Scientific Director, who distributes copies to the BID Director, the NIH Deputy Director for Intramural Research, and the Director, NIH. The report is subsequently reviewed by the Board of Scientific Directors, and a report is made to the Institute's national advisory council on the research reviewed and the results of the review. The impact of the reviews goes in two directions: the comments and evaluations of individual scientists are communicated to them by the Scientific Director; and the latter is responsible for making any necessary changes following recommendations made in the board report. Finally, the Scientific Director reports back to the board, one or two meetings later, his actions in response to the board's recommendations. He is not required to implement every recommendation, but he must either do so or explain why he finds a particular recommendation impracticable or unsuitable.

The process is straightforward and in theory simple, though in practice it becomes complicated and requires a high level of effort on the part of many people, staff and consultants. To illustrate the complexity, one Scientific Director has put together a 77-page loose leaf notebook to describe the review process as used in his intramural program for the information of board members and intramural staff alike. Most of the others have not so far provided such detailed written descriptions for their boards.

D. The intramural evaluation process in practice in 1989.

Starting from the core requirements as summarized above, several variations in patterns of board activities have emerged. Four will be described. The first is the modal pattern, which characterizes nine of the NIH institutes and the two ADAMHA institutes whose intramural programs follow the NIH system. A second has been developed by one institute, NIAID, and merits an individual description. A third, shared by the three NCI divisions with intramural programs (DCBD, DCT, and DCE) is different because reviews are actually made by "site visit teams," chaired by a member of the rather large (15-20 member) division board. Those three boards, in addition to reviewing and approving site visit reports, also perform concept review of contract proposals and are active on some grant matters. The fourth, a variation on the NCI pattern, has evolved in NICHD. Here again, site visit teams make the reviews, and the board deals with those reviews and more general matters about the intramural program.

1. The modal pattern.

Most institutes have separate organizations to handle intramural research and extramural grant and contract programs, so that their boards of scientific counselors can confine their efforts to a review of intramural research. Most boards also want each scientist to describe his own work and answer questions about it before the board. Hence the most frequent pattern of board action--the modal pattern--embodies those features.

To characterize this process it is useful to describe a composite board in action, which in most respects will be similar to the boards in nine NIH institutes. Each of the nine will differ in minor ways from this composite, but in essence they are similar enough to be described together. The descriptions will be chronological so that the full scope of board actions can be seen.

(a) A laboratory or branch is selected for review (or two labs, depending on size). Reviews are scheduled several years in advance, since each lab is to be reviewed at least every four years. The selected laboratory is notified to begin preparations for the review.

(b) Dates for the review are set up in consultation with board members, usually at a preceding meeting, or by telephone. Any ad hoc consultants needed to provide additional expertise for review of the laboratory in question are selected, by the scientific director or by him in consultation with the board chairman, and invited to the meeting.

(c) Under the guidance of the scientific director, the lab chief and lab scientists prepare the usually voluminous set of written materials which are sent to board and ad hoc members a month or so in advance of the board meeting. By studying these loose leaf notebooks the visitors can be well prepared to understand and appraise the research presented to them. The comprehensive nature of the advance written material can be seen from the following list, all or most of which is sent by each institute.

- For each scientist being reviewed, a CV, bibliography, summary of recent research and plans for future research, and recent reprints.
- A staff list of the laboratory.
- An organization chart of the IRP or program and the lab.
- The annual report of the laboratory for the previous year.
- The last board review of that laboratory, probably four years earlier.
- The laboratory budget (by some institutes).
- Drawings showing laboratory space.
- A list of intramural research contracts.
- A meeting agenda and list of board members and ad hoc consultants.

(d) The meeting. All intramural reviews are done at a meeting of board and ad hoc members where scientists and reviewers meet face to face. None are done by mail. The meetings occur twice a year, in Bethesda for most reviews, or in Research Triangle Park, North Carolina (for NIEHS), Baltimore (for most of NIA), or Hamilton, Montana, for the Rocky Mountain Laboratories of NIAID. In general they last two days (1-1/2 to 2-1/2), a period made up of a varied mix of oral presentations, questions, interviews, executive sessions for board discussions and report drafting, and often a final feedback session for institute and NIH officials.

Our composite board begins its meeting with an executive session from 8 to 10 P.M. on day 1, attended, in addition to board and ad hoc members, only by the scientific director, his deputy, his

clinical director, and sometimes the institute director. The scientific director briefs the group on the general scope of the intramural program, especially changes since the last meeting, and answers questions about budgets, NIH leadership, Congressional pressures, etc. The review scheduled for the next two days is brought up and the scientific director outlines any issues or problems he wants the board to attend to. To share the burden of producing a report, the chairman usually assigns board and ad hoc members to the roles of primary and secondary reviewers. They will attend closely to the scientists they have been assigned to and will draft a report--description and evaluation--on each.

At nine the next morning the group convenes for the first all day session. The opening may be somewhat ceremonial, with the institute director in attendance, and in some institutes the scientific staff of the laboratory being reviewed, to see and hear the board and to hear their colleagues report on research. (Scientific Directors and Boards differ in the importance they attach to allowing staff to be present as spectators at the reporting sessions.) After 30 minutes or so of general briefing, the lab chief gives an overview presentation for his laboratory, characterizing the laboratory program and probably touching on the presentations to follow. He and the others may be questioned during or after his talk--the atmosphere is informal and what the board wants in the way of information they get. Following the lab chief, the other independent investigators each take 20 to 30 minutes, followed by 10 to 15 minutes discussion, to describe the research they have been doing, summarize what they have accomplished and its significance, and then outline the directions they intend to pursue subsequently. They may be closely questioned, and will be if their account is not clear, if there are questions about the significance of the problem or the methods used, or if other discrepancies are noted. At times very superior research is the subject of much discussions too, because board members can be as interested in exploring the best as in criticizing what appears flawed. They do not have the narrow task of putting a grade on each scientist and his research, and then going home. They are interested in the whole program in which they are advising, and their aim is high quality for the long term, not just distinguishing between the sheep and the goats, if any. It is worth saying that many times it is a pleasure to watch a good board operate, and to observe the interchanges with the scientists.

At noon all leave but the board, for whom a buffet lunch is likely to be brought in and an executive sessions begins. The morning's program is reviewed, its strengths and weaknesses pointed out, and a consensus begins to develop about the way the research is to be characterized in the report and what recommendations if any, are to be made. After an hour and a half or so the board reconvenes in reporting session for an afternoon of further presentations and discussion. At four P.M., the board may take an hour to visit the

laboratories and talk to younger staff members or students, before returning for a 5-6 P.M. executive session to review the afternoon's program. Some boards then have dinner and spend the evening writing drafts of their observations and evaluations; a few boards have a social evening and dinner with the scientific director and others in the host institute.

The second day follows pretty much the pattern of the first. If only one lab is being reviewed the second morning is probably a drafting session. If two labs are under study the second will consume most of the second day, with a couple of executive sessions. The second evening will clearly be an evening for writing, in preparation for a feed-back session on the third morning. At this session the members of the board read their evaluations for the benefit of the scientific director, institute director, deputy director for intramural research, and possible other officials, and entertain any questions or other opinions. There are few of the latter.

At one of the executive sessions the scientific director reports to the board on actions taken as a result of the board's recommendations at its previous meeting. Sometimes this report is in writing, but more usually it is oral.

2. The NIAID Format.

Review of the NIAID intramural program by its board of scientific counselors differs from the composite format just described in that it places heavy reliance on one-on-one interviews of individual scientists by board members. Formal oral presentations are generally limited to those by lab chiefs and perhaps section chiefs.

The NIAID board has 8 members, a typical number, and usually eight ad hoc members, where most boards have 4 to 6. Prior to the meeting each member receives a 27-page "Information Resource and Reference Manual" which summarizes board duties and responsibilities, and such program information as organizational charts, personnel information, travel provisions, maps, and a description of the meeting format. In addition, the member receives the usual information about the lab to be reviewed--research summaries by the lab chief, a description of each project in the laboratory, and information concerning personnel involved, collaborating units, publications, and future plans.

Also included are c.v.'s for each scientist who is to be interviewed and a meeting agenda. The Scientific Director has already assigned primary reviewers for each scientist, and those assignments are tabbed in the lab book.

The meeting lasts 2-1/2 days, and it will review one large lab or two or three small labs. After a 30-minute opening executive

session the first morning the lab chief presents a summary of his laboratory program, a task some lab chiefs share with one or more section chiefs. Potential candidates for tenure are also given time to present their work. At lunch the scientific director states his questions or concerns about the laboratory and lists the individuals being considered for tenure or promotion. He considers this a very important session. The afternoon is devoted to individual interviews, done in the laboratories. Every scientist who has been at NIH for two years or more is interviewed twice, tenure candidates and lab chiefs and section heads three times. Each member of the board will conduct 6 to 7 interviews, all individually. Most last 30 minutes. The staff seem to like the interviews and some comment that they don't last long enough. Interviewers also examine lab notebooks and any posters available.

In the evening the scientific director entertains the Board, lab scientists and institute officials at his home.

The second morning is used to complete the interviews. Lunch is again a working session, during which the scientific director gives an oral follow-up on the previous review and distributes the written response of the lab chief reviewed. The scientific director also gives a "state of the institute" report, and presents contract renewals for review.

In the afternoon final interviews are completed by 3:30 or 4:00, followed by an executive session into the evening to write up each individual scientist, discuss individuals, sections, and the laboratory.

It is noteworthy that each board member writes out an appraisal of each scientist he interviews, and that these write-ups are for the information of the Scientific Director and the scientist concerned, but not a part of the official report. Any significant evaluations are, of course, included in the final report.

At 8:30 on the third morning board members meet to read their draft reports to each other, and then meet privately with each lab chief. No outsiders are present in this feed back session - even the scientific director stays away. The board summarizes for the lab chief the essence of their report on his unit and gives him ample time to explain or argue with them. The lab chiefs take full advantage of that opportunity, and it is often a productive session. After this the board welcomes outsiders - the institute director, scientific director, deputy director for intramural research, and possibly others, and summarizes their reviews and recommendations on each laboratory involved.

All reports have now been written and are left with the scientific director for preparing final drafts and return to board members for editing. They return the edited drafts within two weeks.

The final stage is reporting back to the scientists the comments by the board. This the scientific director does himself, meeting individually with each of the staff people reviewed, over a two to three month period, and going over with him or her the appraisals written by board members, which are given to the scientists. The scientific director supplies all this information to section chiefs and finally to lab chiefs. And then, at the September meeting of the National Advisory Allergy and Infectious Diseases Council, he presents to the Council a status report on the intramural program and the activities of the board of scientific counselors. The laboratory book and the board report are available to the Council.

3. The NCI System.

The three intramural research programs of the National Cancer Institute differ from those of the rest of the NIH in that each is organized into a Division which includes a number of grant and contract programs. Each Division has a board of scientific counselors which oversees not only the intramural labs and branches but also contract programs and some grant programs. As a consequence of this organization, as well as certain preferences on the part of NCI leadership, there are characteristic differences between NCI and most of the other intramural programs in the way research is reviewed and evaluated. The differences include:

(a) The boards of scientific counselors are larger, from 15 to 20 members, than are other boards, and meet three times a year, rather than twice.

(b) The boards themselves do not review laboratory research programs--that is done by site visit teams, each chaired by a board member and including one or more additional board members plus 6 to 10 ad hoc members. Site visit teams usually review only one laboratory, and there may be 3 to 6 such visits a year.

(c) The site visit team reports, prepared in the usual way, are presented by the chairman of the team to the board of scientific counselors for discussion and acceptance, modification, or rejection. After approval by the Board the reports are given to the division director (scientific director), NCI director, NIH officials, and the Board of Scientific Directors. Each laboratory chief receives a copy of the report on his lab, and he communicates selected portions to the scientists reviewed.

(d) The site visit team members are generally selected by the chairman of the team, who himself is usually appointed by the chairman of the Board. The scientific director makes suggestions on all this; but the choices are not his. He is thus somewhat further removed from the evaluation process than are most scientific directors outside NCI.

(e) The NCI intramural review process is described in some detail in a 9-page printed pamphlet, and the Division of Cancer Treatment has developed its own detailed loose leaf notebook on "Procedures for Review of Intramural Research," with time schedules, sample formats, and full explanations of all phases of the process in some 75 pages.

(f) The NCI division directors provide more detailed information to their boards and site visitors about laboratory space and budgets than do most other scientific directors, at least in part in response to requests from board members and site visit teams.

(g) The format of site visit team meetings is conventional, with presentations by scientists, discussions and questions, and executive sessions to discuss findings and to draft reports. Laboratories may be visited by site visitors if they wish.

(h) As with other institutes, board recommendations are carefully reviewed and responded to orally and in writing.

(i) In general, the system of evaluation used by the NCI Divisions is somewhat more formal, more isolated from the scientific director, and more elaborately planned and organized than in the earlier described modal system. Though the NCI Scientific Directors like their present format, not all of the other scientific directors find it suitable for their programs.

4. The NICHD Variation.

The NICHD reviewing process is a variant of the NCI patterns in that actual lab evaluations are carried out by site visit teams who report back to the 9 member Board of Scientific Counselors. The special characteristics of the NICHD approach are as follows:

(a) The 9 member board meets twice a year for one day. It does not review grant and contract programs. During the one-day meeting the scientific director briefs the board on the state of the intramural program, doing what he calls "reviewing the whole program" at both meetings each year. Usually one scientist gives a broad scientific report. The afternoon is spent going over reports from previous site visits and the responses to them by lab chiefs and the scientific director.

(b) Site visit teams are chaired by a member of the board, who selects members of his team from a list that includes his own nominations as well as those suggested by the scientific director. There are usually three site visits a year, each reviewing one lab. A thick information book is supplied a month before the meeting, with each scientist to be reviewed providing a 10-12 page single-spaced account of his research-- problems, methods, results, conclusions of past work, and future plans. Also

included are the usual c.v.'s and bibliographies, staff lists, and resource information (budgets, space, positions).

(c) The site visits usually last 2-1/2 days, Sunday night through Tuesday. On Monday, scientists present, usually for an hour each, all day, and the board begins to draft reports in the evening. On Tuesday morning small teams of site visitors (a primary and 2 secondary reviewers) visit each scientist in his laboratory. They will interview the scientist and other laboratory staff, including post-docs, and even students. Writing of the report occupies the afternoon, and is almost complete by adjournment at 4 to 5 o'clock.

(d) The site visit report is edited and finalized in the usual way. Within two months the lab chief makes a written response to the report's recommendations, and this is reviewed by the Board at the same time they review the report itself. A year later the scientific director reports orally to the Board what has happened to the lab.

In a way this approach combines some features of the modal system, the NCI method, and the NIAID format. The NIH has encouraged institutes to develop appraisal methods that they feel are especially appropriate for their own research programs.

E. Conclusion

A few concluding remarks are in order.

1. Review and evaluation as now carried out in the NIH intramural research program require a major investment of time, energy and money for research staff and administration. Such use of program resources seems justified.
2. Without exception the institutes and their scientific directors take seriously the task of outside evaluation of their intramural programs. It is a high priority for all, at the top of the annual agenda. As one scientific director recently said, "We don't want the scientists to write grant applications, but we do want them to feel that they've been subjected to a very rigorous review."
3. There is no ready way to compare evaluations by the boards of scientific counselors with those of study sections in the extramural program. The programs are differently structured and the reviews serve different purposes. The one (extramural) reviews grant applications to guide funding decisions. The other (intramural) reviews research retrospectively (with an eye also on future plans) to assist the scientific director in program management. It has important long-term (institutional) aims as well as helping in short term decisions.
4. The recommendation by the IOM that the reviews and evaluations by

boards of scientific counselors be "monitored" by a subcommittee of the Director's Advisory Committee seems susceptible to several interpretations. We have felt that the currently envisaged analysis by a subcommittee of the Director's Advisory Committee into the nature and quality of the current procedures for review of intramural research addresses the IOM concerns.

APPENDIX G

Comparison of Provisions in Chapter 3005, NIH Working Paper Proposals and Consultant Panel Recommendations

Appendix G

Intramural Review: A Procedural Comparison

Issue	NIH Manual, Chapter 3005
Boards of Scientific Counselors: Composition, Selection and Use	Boards of scientific counselors nominated by scientific director (with the exception of NCI), approved by the institute director, and the Deputy Director for Intramural Research, NIH, and appointed by the Director, NIH. Chairperson selection, the number of members and their terms is not stated.
Ad hoc Reviewers	Ad hoc consultants used as the scientific director deems necessary.

Working Paper

Board of scientific counselors members nominated by the scientific director with advice from the chairperson of the board; a final list is presented by the institute director and appointed by the Deputy Director for Intramural Research, NIH.

The chairperson is selected by the scientific director, with the advice of the institute director.

Six to eight members serving 4-year terms.

Ad hoc reviewers selected by the chairperson, board of scientific counselors, with advice from the scientific director.

Panel Report

Nominees selected by the chairperson of the board of scientific counselors with the advice of the scientific director (with the exception of the NCI). The institute director and the Deputy Director for Intramural Research, NIH, provide a final review and approval. Appointments are made by the Director, NIH.

Selection of chairperson not stated.

The institutes should, to the extent possible, increase the number of individuals serving on their boards.

The term of office should be increased to 5 years.

Upon completion of their appointment, scientific counselors should be surveyed on issues of program quality and the scientific review process.

Ad hoc reviewers should be selected by the chairperson, board of scientific counselors, with the advice of the scientific director.

Issue	NIH Manual, Chapter 3005
Review Format	<p data-bbox="906 425 1403 808">Organization and structure of meetings... will be left to the discretion of the scientific director. Past formats include: oral presentations to a plenary session of the board of scientific counselors, individual interviews by board of scientific counselors members or consultants, and small group interviews. The reviewers should be given the opportunity to visit the research facilities, if they wish.</p> <p data-bbox="906 828 1403 1040">Evaluations must address, at a minimum, the following questions: are good questions being asked, are approaches appropriate, and are the resources available appropriate to the accomplishments to date?</p>

Working Paper

Within certain specific requirements..., each institute should be allowed to develop its own procedures. The Deputy Director for Intramural Research, NIH, will evaluate the details... to assure that the uniform requirements of the NIH are met and to communicate the experiences of the different processes to all of the scientific directors.

Reviews must be held at least semi-annually. Each laboratory and branch must be reviewed at least once every 4 years. At a minimum, each tenured investigator... must be reviewed.

Panel Report

Within certain specific requirements, each institute should be allowed to develop its own procedures for the organization and structure of the review meetings. The Deputy Director for Intramural Research, NIH, should evaluate the procedures to assure that the uniform requirements of the NIH are met and to communicate the experiences of the processes to all of the scientific directors.

The boards of scientific counselors should provide evaluation and advice on science, tenure and promotion decisions, resource allocation, specific projects including new areas of development, and other administrative matters.

Uniform standards for scientific review procedures should be developed and codified.

Issue	NIH Manual, Chapter 3005
Information Provided Reviewers	<p>For each laboratory/branch being reviewed: (a) a list of all employees to include name, occupational specialty, type of appointment and grade; (b) a list of all contracts.</p>
	<p>For each scientist: (c) current <i>Curriculum Vitae</i> and bibliography with recent relevant reprints; (d) summary of current research and statement of future plans; (e) the amount of technical and postdoctoral support.</p>
	<p>Procedures shall require that the reviewing entity be provided a written description of the research to be reviewed. The <i>Conference Report</i> for Section 413(b)(7) of the PHS Act notes that "the written description should present the overall past accomplishments of the laboratory and its investigators since the last review was conducted. The written description might also present: the general aims, objectives and projected directions of the research projects to be conducted; appropriate background information on possible future research projects; a brief summary of the general research plan; and an indication of the importance of the research projects."</p>
	<p>A copy of the last board of scientific counselors review of the laboratory/branch should be available to the board.</p>

Working Paper

For each laboratory/branch reviewed: a summary of the administrative organization... including personnel, space allocations, budget information, contract support, and Cooperative Research and Development Agreements.

For each scientist: a short written summary of accomplishments since the last review, a precis of ongoing work, a short statement of future plans, a *Curriculum Vitae*, a bibliography of the last 5 years, a few representative reprints, enumeration of support personnel, and space assignment.

Panel Report

For each laboratory/branch reviewed: all board members should be provided with a summary of the organization of the laboratory to be reviewed, the various sections, all personnel, space usage, operating budget, and outside contracts and Cooperative Research and Development Agreements.

Each scientist being reviewed: should supply details of ongoing work, a curriculum vitae, reprints of the 3 to 5 most important recent publications, and an analysis of the amount of support staff and space that the scientist uses.

Scientific counselors should be provided with orientation guidelines that describe the review procedures, the goals of the process, and the responsibilities of the counselors. These guidelines should be published by the Deputy Director for Intramural Research, NIH.

Issue	NIH Manual, Chapter 3005
Board Report and Follow-up	<p data-bbox="880 445 1369 610">The report of the board of scientific counselors is to be a narrative critique from the chairperson of the board, following the outline preferred by the scientific director.</p> <p data-bbox="880 637 1384 943">Within 4 months, the board of scientific counselors report is sent to the scientific director who transmits it to the institute director, the Deputy Director for Intramural Research, NIH, and the Director, NIH. The Office of Intramural Affairs sends to NIH Board of Scientific Directors and schedules discussion.</p> <p data-bbox="880 1005 1384 1171">The scientific director reports back to the board of scientific counselors on actions taken or explains why it was found impossible or inadvisable to follow the recommendations of the board.</p>

Working Paper

Before the board adjourns, an oral summary will be presented to the scientific director, with the institute director and the Deputy Director for Intramural Research, NIH, invited to attend.

The board of scientific counselors will provide a written report to the scientific director within 1 month of the review. Relevant portions of the report are shared by the scientific director with the laboratory/branch chiefs for discussion.

Within 6 months of the review, the scientific director responds to the board of scientific counselors indicating areas of agreement and disagreement and possible changes that may occur, transmits the report and his response to the institute director, the Deputy Director for Intramural Research, NIH, and the Director, NIH. The report is distributed to the Board of Scientific Directors, and discussed at regularly scheduled meetings.

Panel Report

Before the board adjourns, an oral summary of the review should be presented to the scientific director, the institute director and the Deputy Director for Intramural Research, NIH.

Within a month of adjournment, the board should provide a written report of its review to the scientific director. Those portions of the report that pertain to particular laboratory/branch chiefs should be provided to them by the scientific director. The scientific director and the laboratory/branch chief should discuss the evaluations and recommendations in the report.

Within 6 months of receiving the board's report, but prior to the next meeting of the board, the scientific director should respond to the board indicating areas of agreement and disagreement and any possible changes that may be undertaken. A copy of the report and the response of the scientific director should be sent to the director of the institute, the Deputy Director for Intramural Research, NIH, the Director, NIH, and the institute's national advisory council.

Issue	NIH Manual, Chapter 3005
Board Report and Follow-up (cont'd)	The institute annually transmits the board of scientific counselors reports and the results of its reviews to its national advisory council.
Review of Scientific Directors	"Every independent intramural scientist... must be reviewed and evaluated." The scientific director is <i>not</i> specifically mentioned.

Working Paper

After 1 year the scientific director provides the Board of Scientific Directors with a summary of results of any actions taken.

The scientific director annually presents the institute advisory council the written material reviewed by the board the previous year and the board's reports.

[E]valuation of the performance of the scientific director is inherent in the aggregate of the reviews of the laboratories and branches... Once every 4 years, the board of scientific counselors chair provides to the institute director a report evaluating the review process, the program's overall direction, and its major accomplishments. The institute director may request an evaluation of the scientific director by the chairperson each year.

Panel Report

No later than 1 year after the review, a written response should be provided to the board of scientific counselors by the scientific director summarizing the results of any actions taken.

The institute's national advisory council should be provided an overview of the institute's intramural research program at least once a year. The overview should include, at a minimum, a discussion of the board's report and the response of the scientific director.

The scientific and administrative performance of the scientific directors should be evaluated every 4 years by the boards of scientific counselors. The chairperson of the board of scientific counselors should provide the institute director with a written evaluation of the scientific director, including a discussion of the overall direction of the intramural program, and the efficacy of the review process. The institute director may request an evaluation of the scientific director by the chairperson each year.

